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Food Safety Strategic Elements: Evaluation Synthesis Findings and Research Needs

Final Report

Prepared for

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Planning and Evaluation
Room 447D, Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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Center for Regulatory Economics and Policy Research
Research Triangle Park, NC 27709

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Executive Summary

Since 1999, an interagency task force has been working toward a comprehensive national Food Safety Strategic Plan to reduce the annual incidence of acute and chronic foodborne and waterborne illness by further enhancing the safety of the nation's food supply. The plan will be used to set agency program priorities, improve interagency coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, strengthen prevention and intervention strategies, and develop performance measures to show progress.

The purpose of this evaluation synthesis is to identify research needs and directions for enhancing our knowledge base in food safety. Using the President's Council on Food Safety's Draft Preliminary Food Safety Strategic Plan as a starting point, the first step of the evaluation synthesis process consisted of identifying elements that are critical to achieving the draft food safety goals and objectives. Although the scope of the Council's Strategic Plan for Food Safety is comprehensive and includes microbial, chemical, and physical hazards, the primary focus of this evaluation synthesis and the present report is limited to microbial hazards.

In the process of conducting the evaluation synthesis, a subset of eight key elements was selected:

- Emerging Foodborne Diseases
- Integrated Surveillance and Early Warning Systems
- New Detection Methods for Microbial Hazards
- Patterns of Foodborne Outbreaks

- Market Failure and Regulatory Solutions
- Comparative Risk Analysis and Benefit-Cost Analysis
- Communicating Risk
- Consumer Attitudes, Knowledge, and Practices

The publicly available (and primarily peer-reviewed) scientific literature was evaluated for evidence of the efficacy and effectiveness of each element and its potential contribution to the overall strategic plan. Based on the findings from a critique of key literature on these eight strategic elements, information gaps and research needs were identified. The evaluation synthesis methods and approach are detailed in Section 1 of this report. The findings from a critical review of the scientific literature on the eight elements are presented in Section 2 followed by a discussion of organizational models applied by seven countries in their efforts to consolidate their food safety activities.

Section 3 presents our observations on gaps in our food safety knowledge base, an assessment of research needs, and a discussion of observed future research directions. Our observations on research needs were based on the systematic review of available peer-reviewed scientific literature on the eight key elements; an assessment of the methodologies used in those studies and the limitations of the research; an evaluation of the efficacy and effectiveness of each element and its potential contribution to the overall strategic plan based on the review findings; and an identification of gaps in our current food safety knowledge. Our observed research needs fall into one of three categories:

- **Primary Research Needs**—areas where information gaps indicate a potential role for additional research,
- **MetaAnalysis**—areas where research provides a sufficient base for conducting metanalysis, and
- **Further Evaluation Syntheses**—areas where evaluation syntheses may help to identify information gaps and research needs.

Overlaps in research directions and needs among many of these strategic elements are striking. The key findings of the evaluation synthesis are as follows:

- Existing gaps in our knowledge regarding emerging foodborne diseases primarily surround our lack of understanding of the underlying mechanisms leading to the emergence of a foodborne pathogen.

- With the establishment of FoodNet and PulseNet, great strides have been made toward the development of an early warning system for food safety. However, continuing research efforts are still needed to identify potential indicators that can signal a food safety problem before it escalates into foodborne illnesses or outbreaks.
- Current surveillance efforts do not offer an integrated strategy for monitoring hazard levels from the farm through consumption, nor are they adequately linked to the public health outcomes associated with those hazards. A need exists for developing a cohesive surveillance system established on integrated information systems and electronic data systems that link surveillance in foods to surveillance in human populations, as well as cohesive national, state, and local foodborne monitoring systems.
- Methods for describing and discriminating real-time patterns of normal versus unusual/abnormal pathogen occurrence along the farm-to-table continuum are needed.
- A more robust early warning system for food safety is needed that signals the existence of a problem before it manifests as human illnesses.
- New immunologic- and molecular-based technologies offer a means for continuous improvement of our food production processes. However, the literature shows that applications of these technologies are primarily limited to the consumption–illness link. High costs and the need for highly-trained personnel may be limiting factors and highlight a need for research to improve the field applicability of these technologies.
- Food production, processing, distribution, and consumption changes have resulted in corresponding changes in the patterns of foodborne outbreaks. Efforts to characterize and quantify the shift from traditional "church-supper" outbreaks to widely diffuse outbreaks can help enhance the timeliness of outbreak investigation efforts.
- Research to evaluate the welfare gains and losses associated with various regulatory approaches, such as command-and-control versus incentive-based interventions, is needed.
- Training of both technical and non-technical individuals in risk communication and crisis communication may be critical to achieving food safety efforts. Efforts should include risk communication for short-term (when a risk requires immediate communication or a crisis is present) and long-term (providing continuous information beyond food scares or crises) needs.

- Research on consumer demographics has increased rapidly, making this area potentially ripe for metanalysis. Future research should consider addressing how to use the information from consumer studies to develop risk communication messages and targeted strategies for effective risk reduction.
- A gap exists between consumer knowledge regarding food safety and actual consumer practices. Research is needed to describe why the gap exists in order to develop measures for eliminating the gap.

The list of observed research needs presented in Section 3 of this report is extensive but by no means comprehensive; the observations represent only a subset of food safety research needs specific to the eight strategic elements reviewed in this evaluation synthesis.

We feel that our observed research needs for the eight key elements studied in this evaluation synthesis constitute the starting point of a two-fold process in developing a food safety research agenda, a process ideally involving stakeholder input. The first step is the idea-generating and feedback phase, of which this step is a component, addressing needed research for microbiological food safety hazards.

Evaluation synthesis is a systematic method for summarizing, coalescing, and interpreting evidence of the efficacy and effectiveness of the strategic elements under review. It is a solid foundation for identifying information gaps and directing future research efforts, all of which are critical to developing a research agenda. Hence, it also becomes a useful mechanism in the first step of the process of generating a research agenda or focus.

The second step is the development of a process for prioritizing the generated list of research needs in line with a strategic plan for food safety. Although we do not address this second step in the evaluation synthesis, another objective of the evaluation synthesis project was to develop a mechanism by which input and feedback could be obtained that would assist efforts to establish research needs and priorities. In this regard, RTI has developed an interactive web-based data collection mechanism that has potential applications in developing a food safety research agenda as part of the evaluation synthesis. It is described in more detail at the end of this report. The prototype was conceived as a potential research planning tool for inviting input, obtaining feedback, collecting and tracking rankings, and storing users' responses in a database for analysis. The system allows generation of reports dynamically by pulling real-time data, thus reflecting the most up-to-date rankings and other information contained in the database. We believe that the prototype can be an effective and timely interactive mechanism for obtaining input toward establishing a food safety research agenda. With minor modifications, the system could be ready for immediate use.

1 Introduction

The President's Food Safety Initiative, announced in January 1997, directed the Secretary of Agriculture, the Secretary of Health and Human Services, and the Administrator of the Environmental Protection Agency to identify ways to increase the safety of the U.S. food supply. In the resulting report, released in May 1997, the agencies recommended a long-range strategic planning effort to coordinate food safety policy and resources, address challenges, and optimize the use of resources.

The President's Council on Food Safety was established in August 1998 under Executive Order (E.O.) 13100 to better coordinate food safety policy and resources. In December 1998, the Council released a document defining the scope of the Comprehensive Strategic Food Safety Plan. The document expanded on the initial focus of the Food Safety Initiative—the reduction of microbial hazards in food and water—to include chemical hazards (chemical contaminants and regulated substances with pre-market approval), physical hazards, and hazards from water used in food production and processing.

The Council was also tasked with developing a comprehensive national Food Safety Strategic Plan to "protect public health by significantly reducing the prevalence of foodborne hazards, thereby reducing acute and chronic illness and injuries through science-based and coordinated regulation, inspection, enforcement, research, and education programs." The Food Safety Strategic Plan will be used to set agency program priorities, improve interagency coordination and efficiency, identify gaps in the current system and mechanisms to fill those gaps, strengthen prevention and intervention strategies, and develop performance measures to show progress.

In January 2000, the Council released a Draft Preliminary Food Safety Strategic Plan for review and public comment. Three food safety goals created the framework for the Food Safety Strategic Plan:

- Science and Risk Assessment
- Risk Management
- Risk Communication

Appendix A outlines the specific objectives and action steps for each goal as detailed in the Council's Draft Food Safety Strategic Plan dated January 7, 2000.

Working with the Department of Health and Human Services (DHHS), Research Triangle Institute (RTI) conducted an evaluation synthesis to complement the research-based objectives of the Task Force and the strategic planning process. The evaluation synthesis process included identifying a set of key elements critical to achieving the draft food safety goals and objectives, reviewing the peer-reviewed or publicly available scientific literature for evidence of the efficacy and effectiveness of each element and its potential contribution to the overall strategic plan, and—based on the findings—identifying research directions for enhancing our knowledge base in food safety.

1.1 OVERVIEW OF THE REPORT

This report presents the findings of an evaluation synthesis that consisted of several phases: an initial search of the food safety literature to determine the key elements for enhancing food safety; a thorough literature search of publicly available and, in most cases, peer-reviewed scientific research on a subset of eight key/strategic elements; a critique of the literature and methodologies relative to each strategic element; the development of theoretical integrations of the scientific research literature related to select strategic elements in order to derive an accurate picture of our current state of knowledge; the identification of gaps in information; and our observations regarding research needs and future research directions.

The main purposes of the report are to

- describe the background and methodology of the evaluation synthesis;
- detail the findings from a critique of key literature on eight selected strategic elements and review the organizational models used by countries in consolidating/coordinating their food safety activities; and
- based on the findings of the literature review, identify gaps in our information regarding these food safety elements and outline our observations on research needs and directions for enhancing our knowledge base.

Section 1 describes the purpose of this evaluation synthesis and details the approach and methods used. Section 2 summarizes the scientific research literature on eight strategic elements and identifies gaps in our current knowledge regarding each of the selected food safety elements. It is subdivided into four sections: Sections 2.1, 2.2, and 2.3 correspond to the three goals of the strategic plan (Science and Risk Assessment, Risk Management, and Risk Communication); Section 2.4 describes the efforts of several countries in consolidating their food safety activities and the organizational structure adopted to achieve the food safety consolidation efforts.

In Section 3, we outline our observations for future evaluation studies and research efforts based on the critical review of the scientific literature. Section 3 also describes an interactive web-based mechanism developed for the purpose of obtaining stakeholder input on research needs and directions and for subsequently ranking and prioritizing the identified research needs in line with the Food Safety Strategic Plan goals and objectives.

1.2 EVALUATION SYNTHESIS PURPOSE AND APPROACH

Working in close collaboration with DHHS, RTI conducted an evaluation synthesis to provide research-based support of the strategic planning efforts under the National Food Safety Initiative. The purpose of the evaluation synthesis was to provide supplementary research information to the Strategic Planning

Task Force during the process of development of the Food Safety Strategic Plan. An evaluation synthesis brings together existing scientific research and program evaluation studies and assesses and compares the relevant findings for answering questions about the effectiveness or efficacy of a programmatic strategy to achieve a particular objective. Conclusions from evaluation syntheses can be used to help refine statements of strategic objectives in the plan, identify existing programs and new resources required to achieve objectives, and offer evidence in the plan of the likely success of strategies to achieve the objectives.

The first step in conducting the evaluation synthesis was to identify and prepare a preliminary list of strategic elements that were optimally comprehensive and inclusive of the specific goals and objectives included in the Draft Food Safety Strategic Plan. Members of the Strategic Planning Task Force were contacted to determine their specific research support needs. Starting with input from the Task Force and an initial search of the food safety literature, RTI assembled a list of critical elements of relevance to a food safety strategic planning process. During this problem formulation phase, the important policy, regulatory, and service delivery questions for several strategic elements within each goal were then identified. DHHS and RTI subsequently identified a subset of eight strategic elements and refined the policy relevant questions to be addressed. The following strategic elements were studied in this evaluation synthesis:

- Z ***Goal 1: Science and Risk Assessment***
  - X Emerging Foodborne Diseases
  - X Integrated Surveillance and Early Warning Systems
  - X New Detection Methods for Microbial Hazards
- Z ***Goal 2: Risk Management***
  - X Patterns of Foodborne Outbreaks
  - X Market Failure and Regulatory Solutions
  - X Comparative Risk Analysis and Benefit-Cost Analysis
- Z ***Goal 3: Risk Communication***
  - X Communicating Risk
  - X Consumer Attitudes, Knowledge, and Practices

- ***Organizational Models***
  - Efforts of Seven Countries at Consolidating Food Safety Activities (An Update of an April 1999 GAO Report)

Once the key elements were selected and the research review questions were clearly defined, the next phase of the evaluation synthesis consisted of a systematic and comprehensive retrieval of the scientific research literature and program evaluation studies related to the policy-relevant question for each food safety element. An initial literature search of published studies and reports related to a subset of strategic elements was conducted. Several bibliographical databases (including Agricola, Biological Abstracts, CAB Abstracts, ECONbase, Food Science and Technology Abstracts, Medline via PubMed, Microbiology Abstracts, Social Sciences Abstracts, Sociological Abstracts and UnCover); government, industry, and university web sites; and other food safety related sources were searched to identify related publications and reports.

The literature identified for critical review consisted of key scientific research and program evaluation studies from peer-reviewed journals and from publicly available literature directly addressing the eight strategic elements. In many cases, experts in various subject areas related to the strategic elements were consulted in an effort to identify key research studies and reports.

The relevance of each of the identified studies to the policy-relevant questions was assessed, and key research articles and reports were subsequently located and accessed. Efforts focused on an assessment of the research methodologies used, an identification of the limitations of the research findings, and an evaluation of the efficacy and effectiveness of each element and its potential contribution to the overall strategic plan.

Where additional information was needed, targeted literature searches were conducted. The critical review of each research study, including its reference list, yielded further sources of relevant reports that were subsequently accessed. Literature searches continued in this iterative fashion during preparation of a series of narratives summarizing the current state of knowledge on the various strategic elements and addressed the associated policy-relevant questions.

Because of the nature of the strategic elements themselves, the policy-relevant questions raised, and the current state of the science, the evaluation synthesis necessarily consisted of narratives of a qualitative nature. Hence, the focus of the first phase of the evaluation synthesis was on the theoretical integration of multiple scientific studies in the absence of empirical results enabling more quantitative approaches such as metanalysis. The narratives were targeted toward deriving an accurate depiction of the current state of the science and knowledge regarding the strategic elements, and identifying existing programs, information gaps, and new resources required to achieve the goals and objectives of the Food Safety Strategic Plan.

Each review was prepared with the objective of providing information relevant to the goals and objectives of the Strategic Plan, presenting evidence of the likely success of strategies to achieve the objectives, and identifying the information gaps that could be used to focus future research efforts. Draft reports of the critical literature reviews on key elements were circulated to members of the Strategic Planning Task Force for review and further input. For each of the eight critical elements, these interim reports stated a specific research question, summarized the key findings from the literature review—particularly the gaps in our current knowledge base, and detailed the issues identified in the critical review process. Comments and additional questions from the Council served as the basis for refining and expanding the draft literature reviews and directing the evaluation synthesis efforts.

In the final phase of the evaluation synthesis, RTI detailed a series of specific observations for future evaluation synthesis and research directions based on the findings from the critical review of the literature on the eight strategic elements. Our observed research needs are categorized according to the following criteria: (1) Primary Research Needs—areas where information gaps identify a potential role for additional research, (2) MetaAnalysis—areas where research provides a sufficient base for conducting metanalysis, and (3) Further Evaluation Syntheses—areas where evaluation syntheses may help to identify information gaps and research needs. We present the evaluation synthesis narratives and findings in Section 2 and detail the observed research needs in Section 3 of this report.

2 Findings

This section summarizes the scientific research literature on the eight strategic elements listed in Section 1. Sections 2.1, 2.2, and 2.3 correspond to the three goals of the strategic plan—Science and Risk Assessment, Risk Management, and Risk Communication. Section 2.4 discusses the Organizational Models adopted by seven countries (Australia/New Zealand, Canada, Denmark, the European Union [EU], France, Ireland, and the United Kingdom) in their efforts to consolidate food safety activities. Each review was prepared with the objective of providing information relevant to the goals and objectives of the Food Safety Strategic Plan, presenting evidence of the likely success of strategies to achieve the objectives, and identifying the information gaps that could help to focus future research efforts. For each strategic element reviewed, a specific research question is stated followed by a summary of key findings from the literature review—with emphasis on gaps in our current knowledge base—and a detailed description of the issues identified in the critical review process.

2.1 GOAL 1: SCIENCE AND RISK ASSESSMENT

2.1.1 Strategic Element 1.1—Emerging Foodborne Diseases

Research Review Question

What factors are most likely to be associated with the occurrence of new, emerging foodborne pathogens and problems in food safety?

Summary of Findings

The literature in the last decade postulates the existence of a coevolutionary process between humans and their pathogens. Global change has resulted in structural patterns that increase the likelihood of the emergence of new pathogens. Examples are increases in international travel, concentration of populations in urban centers that have outstripped the capacity of local public health infrastructure, changes in technology, expansion of populations into new ecological environments, changes in the host population, and the continual evolutionary adaptations in the agent itself. Foodborne diseases have clearly been affected by changes in technology within our increasingly globalized food industry as well as the emergence of new agents or new variants of old agents. The challenge for regulators is identifying these new agents early.

Description of the Issue

The recent emergence of several foodborne pathogens promotes the consideration that some or all of the factors associated with emerging infectious diseases in general may also be affecting the pattern of emerging foodborne disease. In fact, foodborne problems such as *E. coli* O157:H7, the new variant CJD and Bovine Spongiform Encephalopathy (BSE), *Salmonella* Enteritidis, and *Listeria monocytogenes* are cited as prototypical emerging diseases.

Lederberg (1997) argues compellingly that humans and microbes exist in a coevolutionary process that puts humans at a disadvantage because of our slow rate of genetic adaptation. In Darwinian terms, our species is not competitive in a natural selection struggle between microbes and humans. To exacerbate our disadvantage, ecological systems are evolving and altering such that many environmental, social, economic, host, and agent factors are favoring the emergence of new pathogens. The following factors favoring the emergence of new pathogens were detailed in the Institute of Medicine's (IOM) report on Emerging Infectious Disease (Lederberg, Shope, and Oakes, 1992): (1) ecological change, (2) human behavior and demographics, (3) international travel, (4) microbial change and adaptation, (5) technology and industry, and (6) weakening of public health infrastructure. It is interesting to note though that most examples of emerging diseases have generally not been the subject of observational studies, and causality is often attributed on the basis of descriptive epidemiology.

The daily stream of food imbibed by the world's 6 billion people provides an ample, daily opportunity for contact between human hosts and newly emerging foodborne pathogens. If not for our efforts at mitigation, food consumption stands as one of the most frequently repeated natural points of contact between pathogens and humans. Globalization of the world's food supply; consolidation of animal production, slaughter, and processing; new food harvesting, processing, and preservation technologies and patterns; changes in where and what people eat; and consumer education have all combined to produce a distinct change in the pattern of food consumption and hence foodborne illness over the past 50 years.

Globalization of the world's food supply provides economic benefits and a fantastically wider selection for consumers. However, in terms of disease control programs, globalization minimizes traditional geographic boundaries on old pathogens. Raspberries from Guatemala, cantaloupes and scallions from Central American countries, coconut milk from Southeast Asia, and a Middle Eastern snack food have all been implicated in recent foodborne disease outbreaks in the United States.

Changes resulting in increased host susceptibility also facilitate the emergence of foodborne pathogens as well as other emerging diseases such as multidrug resistant TB. Immunosuppression, an aging population, and malnutrition have all been implicated in the occurrence of many foodborne pathogens including *Cryptosporidium, Toxoplasma, Campylobacter, Salmonella, Listeria,* and *Giardia*. Rising trends in the number of immunosuppressed individuals from HIV infection and new cancer therapy, an upward shift in the age structure of our population, and the occurrence of malnutrition in pockets nationally or globally all contribute to the emergence of new foodborne pathogens.

Robert Tauxe (1997) raises several issues of concern surrounding emerging foodborne diseases. These diseases are characterized by agents that are generally harmless to the animal host but produce illness in the human host, spread rapidly in pandemic form around the globe, and are increasingly resistant to traditional antimicrobial therapy. Foods contaminated with these emerging pathogens look, smell, and taste normal. Visual detection methods do not identify contaminated animals or foods prior to entry into the consumable human food supply. Emerging foodborne diseases occur in a longer and more intricate production, supply, and consumption chain and may be more difficult to control than those that generally occurred in the previous century. Moreover, new food vehicles have been identified with recent outbreaks.

The way in which we identify outbreaks of foodborne disease has changed as we shift away from acute, local events (the traditional common source outbreak; for example, church picnic) to low levels of contamination of widely distributed commercial products. While widespread outbreaks may have existed previously, they may have gone unrecognized until the advent of newly developed molecular methods to resolve the pattern of cases into an outbreak situation.

As with other emerging infectious diseases, foodborne diseases can threaten public health in several forms: a new and previously unrecognized organism may emerge, a previously recognized pathogen may cause disease in a new way, or a pathogen that was formerly under control may reemerge as a threat. Table 2-1, modified from Daszak, Cunningham, and Hyatt (2000), describes the general archetypes for the pattern of emerging foodborne diseases.

Table 2-1. Classification of Emerging Foodborne Diseases by Various Factors

Emerging Foodborne Disease Type	Infectious Agent	New Food Vehicle	Incidence or Geographic Range
1	Emerging	Emerging	Emerging
2	Recognized	Emerging	Emerging
3	Recognized	Emerging	Recognized
4	Recognized	Recognized	Emerging

It is critical to realize that there are many scenarios leading to the emergence of a foodborne pathogen. Emerging foodborne diseases can result from the appearance of a totally new pathogen or from a change in the characteristics of a previously known agent. Thus, *Cyclospora cayatenensis* is a newly discovered agent whereas changes in previously recognized *E. coli* and *Salmonella* species have resulted in well-recognized emerging foodborne disease entities through the identification of new serotypes. Technological advances in our diagnostic abilities can also launch a pathogen from being a rare opportunist into an emerging category causing diarrheal illness in humans.

Emerging pathogens have also crossed over into what were traditionally considered as safe foods because of biological barriers to contamination. During the 1980s, we came to understand that *Salmonella* Enteritidis can actually grow in the presumably protected egg yolk. Since eggs were commonly thought to be "sterile containers," many foods such as eggnog or Caesar salad prepared with raw egg yolks became new vehicles for foodborne outbreaks. Similarly, orange juice, which was unpasteurized but thought to be safe because of high acidity, became a vehicle for *Salmonella* Muenchen in 1999 (CDC, 1999a).

Finally, changes in geographic distribution or incidence can result in the reemergence of well-known pathogens thought to be under control. For example, trichinosis rates have been falling in the United States. However, a recent outbreak has been attributed to undercooking of pork consumed in a traditional meal by Laotian immigrants. In California, human brucellosis has been transformed from an occupational hazard of slaughterhouse workers to a foodborne disease, largely due to consumption of raw milk by Hispanics while abroad.

All these examples point to an essential set of facts: the current epidemiology of foodborne disease is a complex interaction of agent, host characteristics, environment, and food vehicle. Furthermore, because we alter our food production and consumption systems so rapidly, it is inevitable that the patterns of foodborne disease will change. Some diseases will be controlled while others continue to emerge. Hence, rapid recognition of emerging foodborne pathogens through surveillance and the institution of monitoring, prevention, and control as expeditiously as possible will be important components of the solution to emerging foodborne diseases.

2.1.2 Strategic Element 1.2—Integrated Surveillance and Early Warning Systems

Research Review Question

What are the obstacles to developing integrated systems that can track hazards and associated foodborne illnesses from farm to table as well as detect unusual events and unanticipated changes in the frequency and pattern of occurrence of foodborne hazards and illnesses?

Summary of Findings

The literature on surveillance recognizes and supports the importance of both active and passive surveillance systems for food safety. Active surveillance for foodborne disease has progressed with the implementation of FoodNet. However, several gaps in our food safety surveillance systems (i.e., from on-farm production through human outcomes of interest) were identified. Our current surveillance efforts do not offer an integrated strategy for monitoring hazard levels at both the farm and slaughterhouse. Surveillance of foods is likewise integral to the success of food safety efforts and provides data critical to correlating such efforts to human illnesses. However, our present systems do not track hazards from processing through consumption and then finally to the public health outcomes associated with those hazards. The absence of a cohesive surveillance system highlights the need for integrated information systems that link surveillance in food with surveillance in animal and human populations, as well as cohesive national, state, and local foodborne monitoring systems. A review of the literature on early warning systems reveals a need for more robust early warning systems for food safety (i.e., systems that signal the existence of a problem before it manifests as human illness).

Description of the Issue

The modern concept of surveillance, first articulated by Alexander Langmuir, views surveillance as a process (Foege, 1996). As it relates to food safety, the process is concerned not only with outcomes in the human population but also with the occurrence of foodborne hazards in all types of foods, their sources, and the various stages in their conversion to consumable food. The first step in the process involves routine data collection, which provides an ongoing watch on the population. A second critical step is rigorous analysis and interpretation followed by dissemination of results to individuals implementing preventive practices. Feedback on the usefulness of surveillance outputs closes the surveillance loop. Surveillance systems should be dynamic in targeting their objectives, flexible in data collection methods, and timely (a lack of which often severely limits their effectiveness).

Operationally, surveillance involves the systematic collection of disease and hazard reports in a population from health-related professionals; the process is usually *passive* such that clinics, laboratories, or food-related facilities voluntarily submit reports. With *active* surveillance for human foodborne illness, public health authorities contact the reporting sources on an ongoing basis and request reports of new cases (Potter and Tauxe, 1997). Active surveillance usually yields better data but costs more money and is generally applied to a circumscribed area.

Surveillance is often confused with screening or surveys. Surveillance implements a systems approach and is defined as the ongoing systematic collection, analysis, and interpretation of outcome-specific data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease or injury (Thacker and Berkelman, 1988). For example, public health screening employs tests or other methods to sort out individuals in at-risk populations who appear healthy but actually have infection or subclinical disease. Surveys, on the other hand, are epidemiological research activities that examine finite events without any direct tie to action, although the long-term impact of such studies may be great.

Foodborne disease surveillance has traditionally been viewed as a subset of public health surveillance. Therefore, the links between surveillance for foodborne diseases in humans and surveillance for foodborne hazards in foods have only recently received increased attention. Foodborne disease surveillance typically involves reports of suspected foodborne disease cases; laboratory isolations of foodborne pathogens from human biological samples; or monitoring of sentinel communities, where detailed investigations (e.g., case-control studies) are conducted to elucidate the link between consumption of specific foods and subsequent food-related illnesses.

Foodborne hazard surveillance, which is conceptually related to disease surveillance, monitors the conditions that can lead to foodborne illnesses (Guzewich, Bryan, and Todd, 1997). For example, hazard surveillance systems can detect microbial pathogens at various facilities that handle food (e.g., farms, meat and poultry processors, and restaurants). It typically involves the routine collection of data on foodborne hazards in food products and food sources, follow-up data when hazards are present at unusual levels, and the collection of information that helps to define the sources of hazards in foods. Animal health surveillance as it relates to food safety is also a component of foodborne hazard surveillance. Comprehensive animal health surveillance systems were non-existent until the implementation of the National Animal Health Monitoring System (NAHMS) in the late 1980s (King, 1990). Although the need for a national system is often articulated by animal health decision makers, resource limitations constrain this on-farm monitoring system into working with different species in particular segments of the production process on a rotating basis.

Most foodborne disease surveillance uses passive reporting systems based on the voluntary submission of reports from health clinics and laboratories. The completeness of these reports depends on the ability of clinicians to diagnose the illness and on the interest of clinicians and laboratory personnel to report the diagnoses to the appropriate public health authorities. In contrast, surveillance systems such as FoodNet use active surveillance, whereby public health authorities regularly contact clinicians and laboratories to obtain case reports. But because some cases of foodborne illness will remain unrecognized and go unreported, even active surveillance systems are inherently incomplete (Potter and Tauxe, 1997). One of the most striking gaps in our foodborne disease surveillance is at the levels of individuals who have gastrointestinal illness but do not see a physician. Furthermore, physicians also treat gastrointestinal illness symptomatically but do not frequently culture specimens or ask for a wide range of diagnostic tests to capture all foodborne agents including viruses.

Mead et al. (1999), utilizing data from FoodNet—which employs principles of active surveillance—and other sources, estimate approximately 76 million cases, 325,000 hospitalizations, and 5,000 deaths each year, indicating more foodborne illnesses but less deaths than previously estimated. Confidence in these estimates should be tempered by recognition of obstacles to foodborne disease surveillance that occur at every level of reporting; alternate routes of transmission of foodborne agents such as secondary transmission from primary human cases as well as waterborne routes; and foodborne disease caused by agents that have not yet been identified, hence not diagnosed accurately (Mead et al., 1999).

Although foodborne disease surveillance can provide a variety of public health contributions, these generally fall within three categories (Bean et al., 1997):

- implementing disease prevention and control,
- understanding disease etiology, and
- providing administrative guidance.

By identifying outbreaks and their causes quickly, surveillance can lead to early intervention with the food supply to remove contaminated products (e.g., identification of *Salmonella* Agona contaminated cereal (CDC, 1998) resulted in removal from retail shelves) and rectify inappropriate food handling procedures (e.g., undercooking of meats or cross-contamination of vegetables from raw chicken) that contributed to the outbreaks. If too much time elapses between the outbreak and the investigation, the responsible pathogen may remain unidentified.

Likewise, foodborne hazard surveillance can provide similar public health contributions, not only in providing administrative guidance but by preventing or controlling foodborne disease through the recognition of foodborne hazards and through understanding the etiology of their occurrence and transmission in order to institute effective control. The cumulative information obtained through surveillance and the resulting investigations can reveal the magnitude and trends of foodborne diseases, and such information can help policy makers identify optimal prevention strategies (Borgdorff and Motarjemi, 1997). Additionally, the elucidation of disease and hazard "etiology" can help researchers anticipate or recognize new problems, such as toxins in one food that could pose a problem for other foods or toxins that are newly recognized as posing a human health threat.

The Elements of Surveillance

Successful surveillance relies on the basic elements of epidemiology whether monitoring foodborne diseases or foodborne hazards. Specifically, the system must have a defined population so that risk can be determined. Similarly, the surveillance system must also use a clear case definition for reported illnesses (e.g., specific symptoms or clinical measurements) or clearly-defined endpoints (e.g., positive cultures for specific organisms from a human biological sample, from food, or from surfaces in a restaurant or food processing plant).

For temporal trend estimates to be valid, the surveillance system must use standard procedures over time. Apparent changes in trends, for example, could reflect changes in investigation or reporting systems rather than actual increases or decreases in numbers of outbreaks or hazards identified (Guzewich, Bryan, and Todd, 1997). For example, a 1992 change in the definition of an "outbreak" with regard to botulism and some other nonbacterial toxins led to a lack of comparability over time in the number of reported outbreaks (Bean et al., 1997).

Although a failure to standardize can lead to a lack of comparability in reports over time or across populations, maintaining standardization can also be problematic. For example, the use of new technologies for identifying and characterizing foodborne pathogens, such as molecular genotyping as described elsewhere in this report, by definition requires a departure from standard procedures. The use of these technologies may cause a discontinuity in estimated hazard or disease rates over time, and the technologies may not be available in all populations that are under surveillance (e.g., due to funding or laboratory resource constraints); but their use also provides the opportunity to dramatically improve some aspects of surveillance. Similarly, a switch from passive surveillance to active surveillance would almost certainly increase the number of cases detected, but it produces more complete, and probably more consistent, reports of disease or hazard occurrence.

Surveillance systems typically lack the refinement necessary to get a detailed assessment of disease risk associated with consuming various foods. Even if the disease risk associated with consuming a particular food item remains constant and the overall population size remains constant, the estimated disease risk for the total population could change by a change in the *proportion* of people who consume different types of food. Changes in passive (or active) reporting could also increase or decrease due to gradual or abrupt changes in public awareness of hazards.

Other subtle issues, such as confounding, can affect the ability of surveillance systems to characterize the foodborne disease or hazard trends. For example, cryptosporidiosis can arise from consumption of contaminated foods, but it can also result from contaminated municipal water supplies, as occurred in Milwaukee in 1993, or from contaminated swimming pools (CDC, 1994). Because surveillance systems by themselves lack the necessary precision to fully characterize the nature of foodborne illnesses, case-control studies or other approaches are necessary to attain a complete picture of the etiology and occurrence of such diseases.

Need for Cohesive Information Systems

Effective surveillance for food safety requires the coherent assembly of information from different sources. Although collating reports from different populations can enable the detection of multistate outbreaks, complete reporting also entails gathering of additional *types* of data. For example, reports of sporadic cases from multiple states for a common pathogen would not necessarily indicate that the cases were related. But if the pathogen from most cases had the same serotype, then the cases would appear to be part of the same outbreak. Additional information from case-control studies in sentinel or outbreak communities could identify the food that was the likely source of the pathogen. A recent multistate outbreak of listeriosis benefited from many of these outbreak identification strategies (CDC, 1999b). The integration of the disease surveillance data with hazard surveillance data could be critical to completing the picture in a timely manner as to how the outbreak occurred.

Integrating the information from an on-farm monitoring program such as NAHMS with processing, retail food surveillance, residue and antimicrobial resistance monitoring, and subsequently with FoodNet data will be critical for the implementation of a true farm-to-table approach to food safety surveillance. Not only will the data be more reliable if a cohesive surveillance system monitors food from the farm to the table, but such a system will likely provide impetus for the development of a more comprehensive surveillance system in domestic animals (Bush et al., 1990).

Bush et al. (1995) make several salient points that must be overcome prior to integration of an on-farm monitoring program into a cohesive surveillance system for foodborne hazards and illnesses. Many pathogens, capable of producing foodborne disease in humans, produce no clinical disease in animals and are therefore not reportable. Thus, there is often minimal incentive for food animal producers to share data. Furthermore, producers feel as if they have been studied too much and are therefore reluctant to participate in yet another survey whose utility may be questionable from their perspective.

The synthesis of data from different sources not only requires some degree of standardization in the data collection but also depends on procedures for transmitting the information to a centralized location for analysis and timely feedback to risk managers.

Early Warning Systems

By definition, when problems with foodborne illnesses are recognized at the national level, the problem already has a large scope, and the best result that public health officials can achieve is to limit further disease. Ideally, early warning systems could identify potential problems before they evolve into widespread illness. Early warning could include different facets, such as

- recognizing a potential problem in animals before humans are affected (e.g., contaminated animal feed or water or a high prevalence of pathogens in food animals),
- recognizing problems in procedures that could lead to human exposures (e.g., using contaminated water or ice when watering or transporting fruits and vegetables or handling poultry and fruits on the same surface without cleaning in between), and
- identifying an outbreak source quickly enough to allow removal of contaminated food from restaurants and retailers while the outbreak is still local.

Tauxe (1997) points out that the awareness of the need to monitor pathogens in healthy food animals is fairly recent, and monitoring pathogens in the food and water that food animals consume may also be appropriate. If farms show evidence of increasing pathogen prevalence, then prompt intervention might prevent the pathogens from eventually being consumed by humans.

Unfortunately, the epidemiology of foodborne disease agents on the farm is complex and often confusing in its lack of consistent causal associations. At least one investigator has found that the most prevalent serotypes at three finishing farms (*Salmonella* Typhimurium or *Salmonella* Typhimurium var. copenhagen) were not isolated from the breeding or nursery that housed the pigs in earlier phases of production (Davies et al., 1998). Furthermore, management systems designed to prevent continuous cycling of pathogens, such as three-site production, did not reduce *Salmonella* shedding in field situations (Davies, Funk, and Morrow, 1999). There is a clear need for epidemiological field studies that characterize on-farm risk factors related to foodborne hazards. However, the significance of findings from such studies will be discounted by the lack of an integrated system of surveillance at points further down the food chain.

Even an outbreak itself can provide early warning of a potentially much larger problem. An abrupt increase in the isolation rate of *Salmonella* Enteritidis in New England preceded by several years a large multistate outbreak due to contaminated eggs (Tauxe, 1997). Such studies may indicate that Langmuir's characterization of surveillance as a process involving routine data collection and the rigorous analysis of those data, in combination with the early initiation of epidemiologic field studies in response to the two-phase surveillance process, may in fact be the basis of an early warning system for foodborne hazards.

2.1.3 Strategic Element 1.3—New Detection Methods for Microbial Hazards

Research Review Question

What are the promising new technologies for the identification and characterization of foodborne hazards within our current surveillance, inspection, and control systems?

Summary of Findings

In the last decade, two technologies have emerged that may shape the future of food safety: immunologic-based and molecular-based techniques. Both types of methods offer promising potential for more accurate characterization and identification of foodborne hazards in less time as they become increasingly automated and cost-effective. Genotyping methods may also herald the increasingly important role of molecular epidemiology in food safety. A move toward rapid, inexpensive clinical diagnostic kits that remain relatively unaffected by the matrix, the normal bacterial flora, and interference by food ingredients will become increasingly important in providing real-time assessments for managing foodborne hazards.

These new technologies hold tremendous promise for improving not only our surveillance systems but also for continually improving safety in all aspects of the food production process. However, our review of the literature shows that applications of these technologies are primarily limited to the consumption–illness link. The high cost of most molecular procedures and the need for highly trained personnel may be one reason for limited field applications prior to food consumption.

Description of the Issue

Immunoassays, or antibody-based detection assays, have seen changes in technology and automation with a resulting variety of formats. For instance, the enzyme-linked immunosorbent assays (ELISA) format has been developed to detect pathogens and toxins in food. Commercially available ELISAs include *B. cereus*, *Campylobacter*, *Clostridium*, *E. coli* O157:H7, *Listeria*, *Shigella*, *V. cholera*, and for toxins produced *by S. aureus*, *V. cholera*, *C. perfringens*, and *B. cereus*. ELISAs reduce total assay time by 1 or 2 days but most still require 1 to 2 days for enrichment and 2 to 3 hours for the assay. Other immunoassay formats also reduce the detection time. Immuno-based probes are also very fast (1 hour). The probe format follows a simple procedure that requires a short analysis time and does not require the use of specialized apparatuses. Because of these characteristics, the immuno-probe format is suitable for field screening purposes in inspection programs.

Immuno-based biosensors that combine immunoassays with sensing technology show promise as fast, sensitive, reliable, and economical means of detecting food pathogens in real time (Seo et al., 1999). Several immunosensors have been developed, including immunosensors for *Salmonella* (Seo et al., 1999) and *E. coli* (Feng, 1997). These systems are usually portable and offer on-the-spot analysis; however, more research is needed. Although most immuno-based microbiological assays provide fast results, they are less sensitive than other tests (10^5-10^6 cells), detect dead cells, and show interference with food components.

In addition to immunologic-based techniques, numerous *molecular-based methods* are used for epidemiological investigations and for characterizing foodborne pathogens. Molecular methods are classified into two types: genotype and phenotype. Genotype-based methods, also known as genotyping or molecular typing, involve the direct analysis of DNA in chromosomal or extrachromosomal genetic material. The primary advantage of genotyping methods, such as PCR, is high discriminatory power. Because genomic DNA is a stable characteristic (with the exception of plasmids) and its composition is independent of methods of preparation, all strains are typeable. Furthermore, since the analytical strategies are similar, they can be applied to DNA of any source and are amenable to automation.

In comparison, phenotypic methods detect characteristics that are outward expressions of the genetic material. These methods include biotyping, serotyping, plasmid profiles, ribotyping, phage typing, antibiotic susceptibility testing, and bacteriocin typing. Disadvantages for phenotyping methods include the need for specialized reagents, which limits the number of reference laboratories capable of conducting these methods reliably. Other (and perhaps more significant) disadvantages include nontypeability of strains, low repeatability of results, and inability to distinguish between two closely related strains (discriminatory power).

With respect to foodborne microorganisms, both types of molecular-based methods provide information that may be used to determine the relatedness of bacterial isolates, differentiate between strains, and identify specific sources of those strains. As a monitoring tool for viruses, the use of molecular-based methods has been questioned because of the insensitivity of the methods, the likelihood of false-positive results from environmental contamination and false-negative results from inhibitors, and the inability to distinguish between viable and noninfectious viruses (Richards, 1999).

What do immunologic-based and molecular-based methods offer in terms of food safety? Molecular typing will allow determination (or elimination) of a specific agent and source of the foodborne illness. In clinical applications, molecular typing may help to identify whether a link exists between a clinical isolate of a foodborne pathogen and isolates from an implicated food product. This capability is particularly significant for relating outbreaks in humans to a food product and potentially even a herd/flock source. For example, Lin and Tsen (1999) demonstrated a PCR for the detection of *Salmonella* Typhimurium in food and stool samples. The sensitivity reported for this test was as low as 10^0 colony forming units (cfu) per 0.1 gram or milliliter of sample; however, the specificity of PCR varied with the region of detection. False-positive results are possible if an organism contains gene sequences similar to those of the organism of detection.

The ability to study strains using molecular typing techniques may enhance the identification of emerging strains of foodborne pathogens and aid epidemiologic field efforts tremendously. One such method of value is pulsed-field gel electrophoresis (PFGE), whose high reproducibility and discriminatory power make it a good tool for epidemiological and taxonomic studies. Recently, Sulakvelidze et al. (1999) used PCR, PFGE, and antibiotic resistance tests to characterize *Salmonella* strains from three Salmonellosis outbreaks in the Republic of Georgia that were originally thought unrelated. Using *PulseNet,* the researchers were able to link identified strains in three different geographic locations indicating that they were actually part of a single large outbreak. Their results further suggested that a distinct clonal strain of *Salmonella* Typhimurium, one that was extremely virulent and resistant, caused the outbreak.

Molecular typing techniques also hold promise for use in the continuous improvement of our production of safe food from farm to table. However, based on a review of current literature, research on this application is limited. The high cost of most molecular procedures and the need for highly trained personnel may be one reason for limited field applications. In one study (Ralyea, Wiedmann, and Boor, 1998), automated phenotyping and ribotyping techniques were applied at a production facility to track dairy spoilage from microorganisms in a milk plant and identify the source of contamination. Although it is not as discriminating as some other methods, ribotyping uses a common probe, has high reproducibility, and is well-suited to testing at production facilities because it can be automated. In the context of food safety, this type of application has potential for use in determining the persistent source of a food contaminant so that appropriate corrective actions can be taken. Research gaps are evident in the farm-to-table application of these new technologies. Efforts should address sampling methodologies, inferences based on the test results, and specific uses of new technologies in quality control, quality assurance, and HACCP programs.

Advances in rapid methods also offer potential improvements in the application of immuno- and molecular-based methods as part of a HACCP system. Tests that can be completed within minutes or hours would enable processors to take quick corrective actions when pathogens are detected, thus optimizing the HACCP systems that are required by the regulation. Several researchers have developed rapid food safety applications for immuno- and molecular-based methods. Wang and Hong (1999) report an ELISA-mediated PCR for *Listeria monocytogenes* that reduces time required for detection by 2 days. Stefanovicova et al. (1999) applied PCR techniques for the confirmation of presumptive *Salmonella* with a reduction in the time for confirmation to a maximum of 6 hours. Furthermore, they report that results from their PCR method matched those from standard tests identically in terms of distinguishing *Salmonella* from non-*Salmonella*. Although PCR can be fast, it can detect dead cells and a complete PCR system is relatively expensive.

Biosensing for rapid detection of *Salmonella* Typhimurium in chicken carcass rinse samples combines immunoassays with optic technology (Seo et al., 1999). In addition to immuno-based and molecular-based techniques, several other rapid techniques are currently being applied in industry or under current investigation for their applicability. These include such methods as ATP detection; ice nucleation; phage-based assays; and electrical detection, which includes impedance, capacitance, or conductance (Waites, 1997). Edmiston and Russell (1999) apply conductance to enumerate *E. coli* from petrifilm and conclude its potential to meet testing required by the USDA pathogen reduction regulation.

In spite of some disadvantages, both immunologic- and molecular-based methods offer improved sensitivity. Some techniques are affected by the matrix, normal bacterial flora, and interference by some food ingredients, affecting their performance. These methods may also require pre-enrichment or confirmation of microbial identity, although research continues to develop rapid methods. Both types of methods offer promising potential for characterization and identification of foodborne hazards and successful intervention strategies, as they become increasingly automated and cost-effective.

2.2 GOAL 2: RISK MANAGEMENT

2.2.1 Strategic Element 2.1—Patterns of Foodborne Outbreaks

Research Review Question

What are the challenges facing risk managers in the identification and recognition of the pattern and source of foodborne outbreaks?

Summary of Findings

Recognition of the pattern and source of foodborne outbreaks is crucial to maintaining a safe food supply. Pattern recognition depends on the ability to efficiently collect information about the time, space, host, agent, and food vehicle characteristics of the outbreak. Traditional foodborne outbreaks are less frequently the norm because of changes in our food production, processing, distribution and consumption patterns. Additionally, emerging foodborne diseases and intentional food contamination have presented new patterns of foodborne disease.

Description of the Issue

The investigation of an outbreak should determine the possible etiology, means of spread, incubation period, existence and type of carriers, immunity characteristics of the host population, risk factors, seasonality, efficacy of any control programs instituted, and potential for secondary spread.

Recognition of outbreaks can occur in several ways (Reingold, 1998). More often than not, the patient or their relations are the first ones who suspect a problem particularly after a shared meal. Frequently, a physician may notice an unusual number of cases of a disease and alerts the public health department. Routine surveillance data can also point out unusually high numbers of cases indicating a possible outbreak. Increasingly, outbreaks that might not have been previously recognized as associated can be traced to a common source with modern molecular methods.

The pattern of any foodborne disease should be characterized by gathering data on its occurrence over time and space, by host and agent characteristics, and by food vehicle. The key to pattern recognition is to identify these factors (time, space, host, agent, food vehicle) in surveillance data, through clinical observation or other sources of information. It is also essential to calculate appropriate and relevant attack rates.

Foodborne outbreaks may present in several different forms. Three outbreak patterns are notable: the traditional common source outbreak, emerging foodborne disease, and intentional food contamination. The most traditional pattern is the common source outbreak (or so-called “church supper” foodborne outbreak). In such cases, a common food source is contaminated with a specific pathogen or its toxins or other foodborne hazard. Thus, the pattern is usually discrete in time and space. However, recent changes in our food production and distribution systems (e.g., intensified production and processing systems, changing consumption patterns) have resulted in a more widely diffused pattern of foodborne outbreaks.

In this more diffuse pattern, surveillance systems such as PulseNet and FoodNet are critical to the identification of an outbreak, which starts with tying several clusters in separate geographic areas over a span of time to specific molecular characteristics of an agent. The food processor, distributor, or retailer may also possess critical data that lead to the identification of the source, vehicle and agent in this type of outbreak. Other key questions in the accurate identification of a diffuse outbreak include whether there is more than one outbreak or more than one food vehicle within a given time period.

Over the past two decades, the recognition of foodborne outbreak patterns has been further complicated by the emergence of new foodborne pathogens. In general, these emerging foodborne outbreaks present a challenge in pattern recognition since they have not been previously described. A more detailed discussion of the issues related to emerging foodborne diseases is presented in Section 2.1.1.

Another presentation of outbreak patterns relates to intentional food contamination. This type of outbreak is *extremely* rare. However, it presents unique challenges, which primarily revolve around distinguishing intentional contamination from “true” foodborne outbreaks.

Deliberate acts of food contamination using a biological agent are rare in the United States. Since 1984, there have been two deliberate food contamination incidents resulting in a total of 765 short-term illnesses and no associated deaths. The bacterial pathogens used in each of these cases were *Salmonella* Typhimurium and *Shigella*. In September 1983, deliberate contamination of a salad bar with *Salmonella* Typhimurium resulted in 751 cases of foodborne illness. This outbreak was particularly interesting because the purpose of the intentional attack was to alter the results of a local election. The second case occurred in October 1996, when a disgruntled employee used *Shigella* to contaminate pastries served in a laboratory affecting 13 individuals.

Threats of food contamination with a biological agent are likewise a rare occurrence in the United States. From October 1995 through March 1999, there were three threats of deliberate food contamination. Upon investigation, two of the threats turned out to be hoaxes.

The importance of our public health system and infrastructure to bioterrorism was highlighted in the First National Symposium on Medical and Public Health Response to Bioterrorism held on February 16-17, 1999 in Arlington, VA (CDC, 1999c). The first responders in intentional foodborne outbreaks are the public health and medical communities. Physicians must be able to recognize and report cases that come to their attention; public health officials must be able to conduct investigations to establish the likely site and time of exposure, the size and location of the exposed population, and the prospects for secondary transmission; and laboratory personnel must be able to identify the biological agent (Shalala, 1999). In addition to the public health and medical communities, agencies with food safety responsibilities are also important first responders because they can thwart or limit the potential impact of an intentional foodborne outbreak. An enhanced public health infrastructure must necessarily include those agencies involved in maintaining the safety of the nation's food supply. Their role as first responders to foodborne hazards is critical as it may prevent widespread dissemination of contaminated food.

Potential foodborne biological agents need to be able to survive cooking temperatures that readily destroy most organisms. Foods most vulnerable are those consumed uncooked or ready-to-eat. Post-pasteurization and post-cooking intentional contamination bear the largest potential for bioterrorism since there is generally no additional "kill" step to render biological agents harmless. Toxin-producing bacteria merit special consideration since toxins are stable to heat and irradiation. However, most toxins can be detected via immunoassay.

A recent review of foodborne agents of bioterrorism identified the agents with the highest potential for use in foodborne biological attacks. The list of potential agents included bacterial agents such as Anthrax, Plague, Brucellosis, and Glanders as well as those bacteria that typically cause foodborne illnesses such as *Salmonella*; viral agents including Filoviruses and Hepatitis A; and toxins including Staphylococcal Enterotoxin B, Botulinum toxin, Mycotoxins, and Aflatoxins. Other foodborne biological threats that were included in the high potential group included genetically engineered microorganisms and microencapsulated agents (Christensen, 1999).

Implications of Outbreak Pattern Identification for Our Public Health Infrastructure. Medical preparedness is essential to early recognition of foodborne outbreaks of high consequence. Readiness would involve the education of first responders in the epidemiological principles and clinical/laboratory diagnosis of foodborne outbreaks. Monitoring and surveillance are the keys to early detection of outbreaks, both natural and intentional. In addition to education and awareness, a disease-reporting infrastructure and communication among all levels of public health are also essential components. A robust public health infrastructure could incorporate enhanced surveillance systems, improved diagnostic techniques, efficient communication systems, new vaccines and drugs, and integrated research and training programs.

2.2.2 Strategic Element 2.2—Market Failure and Regulatory Solutions

Research Review Question

What is the role of governmental regulatory activities in addressing the failure of economic market conditions or processes to assure the safety of food products?

Summary of Findings

Consumers are often unable to discern the safety of food when making a food purchase decision. If they were able to at a low cost, then the markets for food products would take into account the safety of consuming the products. Producers likewise may not be able to ascertain the safety of their products. If they could, the costs could be prohibitive or consumers may not be willing to pay for it because it might not be evident. Ultimately, market failures result in a divergence between private and social costs (which include morbidity and mortality). When private costs are lower than social costs, “too much” unsafe food is produced and consumed, and market intervention may be warranted to diminish the gap. According to economic theory, the benefits of regulatory intervention may exceed the costs if a market failure exists.

The broad categories of market interventions include command-and-control (including process standards, product or outcome standards, and mandatory disclosure) and incentive-based interventions (including public provision of information, private bargaining, and product liability). Mandatory disclosure is the only category that may not readily lend itself to food safety due to inadequacies in current technologies for real-time assessment. Product or outcome standards can be viewed as having an incentive-based structure since they provide for producer flexibility. Product liability may not be an efficient means of achieving adequate protection because of the inability of tort liability to provide the economic incentives needed to reach optimal levels of health and safety.

Description of the Issue

A market is that set of suppliers and demanders whose trading establishes the price of a good. Markets may be characterized in several dimensions such as the commodities of interest, the suppliers of these commodities and the supply system, and the users of the commodities and the consumption system. Commodities are valued by consumers for the characteristics they possess (Lancaster, 1974). Since a specific commodity can be viewed as a unique bundle of those characteristics, the value of that commodity to the consumer depends on the specific characteristics of that commodity and the value of those characteristics to the consumer.

Food purchase decisions are generally based on discernable characteristics such as taste, appearance, and nutrition. There is considerable evidence that food purchases would also be influenced by safety characteristics, but actual safety is often difficult for consumers to discern. When product safety information is not readily available (imperfect information), then a system of price–market institutions to sustain "desirable" activities or to stop "undesirable" activities may not be successful. This situation is referred to as market failure. Put another way, market failure occurs when the marginal value of a commodity diverges from its price.

If the level of safety or risk associated with a food could be determined easily (at low cost) by consumers, they could then make "better" food purchase decisions. A "market for safety attributes" would exist—or more accurately—the markets for food products would take into account the safety of consuming the products. However, consumers oftentimes do not have complete information about the safety of food during time of purchase. This is particularly true of microbial foodborne pathogens, which cannot be seen with the naked eye or tested in a timely and accurate manner. Furthermore, even if they become ill and recognize that the cause is foodborne, consumers may have difficulty identifying the specific food source barring an acute onset of foodborne illness. Effectively, ascertaining the quality of a food after purchase may likewise be difficult.

Even producers have imperfect information about the safety of their products (for example, because of the lack of rapid, accurate diagnostic tests for foodborne pathogens). Even if producers could ascertain the level of product safety, they may not be able to recover the higher costs of producing safer food if consumers are unable to recognize the safer product and willingly pay more for it. Further, the costs of producing food with a higher degree of safety may be prohibitive, making it impossible for producers to respond to consumer demand for higher safety. Ultimately, market failures result in a divergence between private and social costs. The social cost of producing an "unsafe" food includes the morbidity and mortality costs that accompany its consumption. The private cost of manufacturing the unsafe food falls short of the social cost. With the private cost lower than the social cost, "too much" unsafe food is produced and consumed.

The lack of information for both producers and consumers results in market failure. Another reason for market failures in food safety relates to the high transaction costs of achieving safer foods. Not only must there be agreement between producers and consumers on the level of safety, but there is also the issue of determining the premium that consumers would be willing to pay for a safer food. Market failure in achieving safer food has been advanced as the fundamental justification for public intervention to improve food safety (Jensen and Unnevehr, 1995). According to economic theory, the benefits of regulatory intervention cannot be greater than the costs if there is no market failure.

Alternative Solutions to Market Failure

When private and social costs diverge, market interventions may be warranted to diminish the “gap” and bring market price closer in line with marginal social cost. Market interventions seek to address the fundamental information problem and can be constructed in different forms. Litan and Nordhaus (1983) distinguish them as command-and-control versus incentive-based interventions with five categories. Process standards (how a product is produced), product or outcome standards (testing and inspection to assure acceptable limits are attained), and mandatory disclosure fall under command-and-control interventions, while public provision of information and private bargaining are incentive-based. Mandatory disclosure is the only category that may not readily lend itself to microbial food safety due to inadequacies of current technologies. Product or outcome standards may further be viewed as having an incentive-based structure since they allow a producer the choice of inputs or technologies. Private bargaining would include voluntary certification programs for small groups of producers with possible public verification.

Strategies for managing risk have centered traditionally on command-and-control approaches or the use of “bright lines” (specific exposure concentrations) that delineate between negligible and unacceptable upper limits of risk. Command-and-control regulatory approaches—which seek to raise marginal private costs of production, in effect to include social costs of unsafe foods into the decision process—have had historical success in many areas, but there has been a recent recognition that additional approaches for improving public health exist that may offer efficiencies. The use of bright lines or single point risk estimates in general can mislead one to think that sufficient knowledge or information exists such that certainty is attained. A strict bright-line approach to decision making cannot explicitly reflect uncertainty about risks, population variation in susceptibility, community preferences, or economic considerations (The Presidential/Congressional Commission, 1997).

Additional regulatory approaches for improving public health should include incentive-based approaches. Environmental examples include tradable permits and tax incentives or subsidy programs for reducing pollution. In the food safety arena, the government could conceptually levy a “tax” on the production of unsafe food (or subsidize the production of safe food) to bring private costs in line with social costs. Other market-based incentives that should be considered as regulatory options include bans or use restrictions, direct economic incentive policies such as the use of special labels or other information provisions to distinguish a product as safe, and alternative compliance approaches that give the industry a choice of how to achieve the required risk reduction while setting a minimum performance standard that must be attained. Each option should be designed specifically to address the market failure motivating the possible need for regulation.

HACCP is an example of a market-based incentive approach that allows industry flexibility in selecting risk reduction options, while setting a minimum standard. HACCP was designed as a process control system, but it can also be implemented as a performance standard. HACCP requires that performance standards be selected for the individual critical control points that are being monitored and controlled, so their effectiveness can be verified. Hence, HACCP as a standards-based approach can function both as a process and as a performance standard. Selection of standards (either process or performance) has significant implications for evaluating food safety policy. Because HACCP is both a process and a performance standard, the mode of implementation of HACCP is crucial to evaluating the economic implications in terms of market efficiency. Setting a performance standard can be efficient by allowing *firms* to choose the least-costly methods (or processes) to achieve the goal. The same does not necessarily hold if the process is restricted by setting process standards.

Alternatively, incentive-based structures could also result in an efficient market solution if the incentive amount were properly set to equate private and social cost. HACCP programs and quality assurance programs can both take on incentive-based structures. For example, some firms may have the ability to produce a safer product at a lower cost. If demand for a product with a higher level of safety exists (for example, by certain high-risk groups), low-cost producers can fill a niche by instituting a public- or privately-sponsored certification program. Over time, such a market provides incentives to develop lower cost production methods for safe food (Jensen and Unnevehr, 1995). Voluntary certification programs also allow development of markets for higher levels of food safety. The equilibrium premium would be determined by the cost of producing a product with the higher level of safety and the value of the improved safety level to consumers.

Finally, product liability has also been used as an incentive-based approach to achieving food safety. The British Food Safety Act of 1990 is an example of such an approach. The statute changed liability laws by adding a "due diligence" defense clause. Food producers can protect themselves from liability by increasing their level of compliance monitoring or quality control (Crutchfield et al., 1997). Arguments against this approach are predicated on the inability of tort liability to provide the economic incentives needed to reach optimal levels of health and safety (Viscusi, 1989). The information requirements for documenting liability suits are high and potentially costly. Furthermore, it is often difficult to establish a causal relationship between the illness, the food consumed, and the source of that food.

2.2.3 Strategic Element 2.3—Comparative Risk Analysis and Benefit-Cost Analysis

Research Review Question

What is the appropriate role for comparative risk analysis (CRA) and benefit-cost analysis in establishing priorities and allocating limited resources?

Summary of Findings

Although the literature reveals opposing views as to whether these methods are necessary and sufficient for designing sensible public policy, there is general agreement in the literature regarding the value of the information obtained from CRA and benefit-cost analysis in guiding the decision-making process. Each method provides a unique and important set of information for risk managers to assist in establishing priorities and allocating resources. CRA provides a means of comparing and ranking risks. Benefit-cost analysis provides a way to estimate the benefits and costs of reducing those risks. However, these decision-making tools should not be perceived as automatically eliminating low-risk hazards from risk management solutions but instead should provide perspective on relative risk and magnitude of consequences for informed decision making.

Description of the Issue

Oftentimes, risk management decisions regarding health and safety must be made even when the information pertinent to those decisions is lacking or highly uncertain. In a 1997 report, the Presidential/Congressional Commission on Risk Assessment and Risk Management proposed a systematic, comprehensive risk management framework that focused on the risks to "human and environmental health and on addressing the benefits, costs, and social, cultural, ethical, political, and legal dimensions of risk reduction options." This section describes two methods that can play an important role in informing the decision-making process: CRA and benefit-cost analysis. Each provides an important set of information which, when used in conjunction with the other, can aid in establishing priorities and in determining the efficient allocation of limited resources.

The Role of Comparative Risk Analysis. CRA (also known as risk ranking or relative risk ranking) is a method used to compare anywhere from two to large numbers of risks. On a programmatic scale, CRA can be useful for allocating budgetary or other resources, identifying problems that require increased attention, or, as applied in the environmental field, obtaining agreement on and support for a particular agenda (Davies, 1995). CRA is also valuable in providing insight into setting priorities for risk reduction, particularly when the objective is to (re)allocate resources between less serious and more serious risks. There are no "cookbook" methods for doing a CRA since it involves a complex mixture of objective science and value judgments. It is for this reason that the process criteria for a CRA become important. Process criteria include who does the estimation and comparison of risks, how risks are defined, and what considerations are relevant for establishing priorities. For example, if priorities are to be established based only on the relative damage to public health, then scientists become critical to the process. However, if risk is defined more broadly than damages, then it may be necessary to involve both stakeholders and non-stakeholders (those with no direct stake in the policy options) in the process.

There are three essential players in CRA, each bringing their own expertise to bear on the process. Technical experts provide information about the health outcomes and severity relative to other hazards. Policy makers provide information about the feasibility of addressing a particular problem as well as the political variability of alternative actions. The public brings a certain set of value judgments, which include dread and perceived gains. Involvement of these key players in the process has been viewed as contributing to increasing support for the decisions that follow from the CRA.

The types of comparisons are likewise broad in CRA and could include foodborne pathogens, geographical areas, proposed solutions/actions, economic sectors, or affected populations. In the environmental area, problems such as air pollution or urban emissions have been the basis of comparison. The choice of comparison category should be based on the purpose for the CRA. Hence, establishing this basic question at the start of the process is critical to its success.

The risk ranking process ranges from one that is heavily determined by scientific estimates of adverse outcomes to one that is highly subjective and driven primarily by values. A good CRA will combine both approaches but neither one to the extreme. There are several ways of comparing risks in a CRA process, including using money as a common metric and estimating the dollar value of each risk (or avoidance of the risk);

and ranking across a common variable such as severity, duration, geographic scope, or number of people affected. Environmental CRA has tended to compare risks within the categories of health, environment, and welfare.

CRA has been used to compare environmental risks and policy activities for several years. Until recently, these federal comparative risk projects focused on the technical analysis of relative risks for guiding regulatory and programmatic priorities. More recently, these comparative risk efforts have evolved into stakeholder processes, thereby linking scientific understanding with public values in decision making. At the local and state level, these comparative risk projects have been used to generate information and data about relative risks to the environment and human health. They have also been used as a process for bringing stakeholders together to incorporate scientific analysis (risk assessment) and public values in policy development. However, neutral, credible science must still remain the foundation of CRA and stakeholders play an important role in assuring that CRA and risk assessment are accurate, useful, and transparent.

There are limitations to the application of the methodology. CRA does not lend itself to comparison of programs that have an indirect effect on risk such as research and development, administration, and policy planning. The current literature does not provide a proposed method for incorporating these program types in a CRA. Neither is CRA amenable for use in programs targeting the prevention of new sources of risk rather than dealing with existing risks. Food inspection programs are one such example (Davies, 1995). Proposed solutions include estimating the averted risks by comparing with baseline risks prior to initiating the program or to risks existing in other areas or countries that do not have a comparable program. While this limitation of CRA is clearly acknowledged in the literature, it is also recognized that proposed solutions are not optimal because such preventive programs may be the most important and effective for reducing new sources of risk.

CRAs have also been described as a “crude tool” because of the breadth they necessarily must cover. Risk rankings do not attempt to estimate exposure or response but they must make broad generalizations about hazards as well as the populations or ecosystems affected by these hazards.

In general, risk rankings are viewed as important or necessary, but not sufficient, for risk management. Proponents of CRA further caution that risk ranking does not necessarily translate directly into budgetary priorities. Finally, risk rankings do not address the costs of doing something about the risks.

The Role of Economics and Benefit-Cost Analysis. Economic analysis plays an important role in risk management and in informing the decision-making process in several ways. Economics provides valuable information for decision makers by measuring or estimating the consequences of disease and its control and by providing guidelines for evaluating different animal and public health policy options, their cost-effectiveness, and the distributional effects among different groups. At a national level, economics can aid in setting priorities for mitigation—that is, the hazards that take priority in resource allocation decisions—both in total and at the margin. Economic analysis therefore provides a means of identifying and quantifying the tradeoffs that accompany resource allocation choices, recognizing that monetary expenditures often do not represent the true opportunity costs of decisions.

One vital role of economics is that of "gatekeeper" by providing information that helps to determine the efficiency/inefficiency of policies before they are enacted (Antle, 1995). Another is in assisting food producers in understanding how food safety and public perception affect consumer demand for their products, ultimately determining the economic health of their industry. Economics also has a prescriptive role of specifying the most economically efficient way to achieve a given level of safety or maximize hazard reduction for a given outlay of resources (Morales and McDowell, 1999).

Economics can provide valuable information to help risk managers in the efficient allocation of resources to mitigate risk. A critical objective for risk management in food safety is the effective and efficient mitigation of the public health risk (i.e., achieving the desired level of risk reduction at the lowest possible cost or implementing the intervention strategy that results in the greatest net benefit). Identifying the most efficient ways of lowering risk is one role for economics in risk management.

Economics also provides methods for identifying and quantifying the distributional effects of decisions. Gains and losses to industries and consumers can be assessed and inequities identified through welfare analysis. Examples of such distributional questions include how much more will consumers have to pay as product price increases, by how much will risk mitigation requirements raise firms' production costs, and which industry segments will bear the burden of regulatory costs (Morales and McDowell, 1998).

In support of a rulemaking under E.O. 12866, regulatory agencies must conduct an economic analysis of the benefits and costs of a proposed significant regulatory action. A January 11, 1996 document entitled "Economic Analysis of Federal Regulations Under Executive Order 12866" provides a sound and flexible framework for the conduct of economic analysis and highlights the important considerations in analyzing the benefits and costs of regulatory options. Economic analysis should also take into consideration the net benefits and distributional impacts of alternatives.

Quantification of the benefits and costs of regulation can be accomplished by several means. Monetization is one such metric, and the use of outcome measures is another. This section discusses benefit-cost analysis as a methodological example that uses money as a metric and introduces two non-monetizing methods that quantify health effects and the change in incidence of relevant public health outcomes (quality- or health-adjusted life years and risk-risk analysis, respectively).

Benefit-cost analysis is a valuable way of organizing the comparison of favorable and unfavorable effects of proposed policies (Arrow et al., 1996). It is the principal analytical tool of quantitative regulatory impact assessment. Benefits associated with reducing risk can be compared with the cost of reducing risk through benefit-cost analysis. Benefit-cost analysis helps to answer the questions pertaining to what should be done and how best to achieve it.

Benefit-cost analysis uses as a metric a monetary measure of the aggregate change in individual well-being resulting from a policy decision. Individual welfare is assumed to depend on the satisfaction of individual preferences, and monetary measures of welfare change are derived by observing how much individuals are willing to pay (i.e., what they are willing to give up in other consumption opportunities). Cost-effectiveness analysis, a subset of benefit-cost analysis, assumes a given policy outcome (e.g., a specified reduction in number of cases of foodborne illness) and seeks to identify the least-cost means for achieving the goal, taking into account any ancillary benefits of alternative actions (Kopp, Krupnick, and Toman, 1997).

Benefit-cost analysis has its limitations. While benefit-cost analysis can help a decision maker understand the implications of a decision better, it may not be able to prove that the economic benefits of a decision will exceed or fall short of the costs when there is too much uncertainty about the estimates of benefits and costs. But even with limited time, resources, or information, benefit-cost analysis can provide illuminating information on proposed regulations.

The benefits of food safety regulation lie in the reduction in the morbidity and mortality risks associated with consuming foods contaminated with foodborne hazards. The economic approaches to analyzing these benefits attempt to model and attach a value to the reductions in health risk. Several approaches to valuing health risks have been developed. The cost-of-illness (COI) approach is frequently used to value morbidity and measures the medical costs of an illness plus the foregone income due to lost worktime. The COI approach has several shortcomings and is a lower bound estimate of the willingness to pay for reduced morbidity (Harrington and Portney, 1987).

The value of a statistical life (Landefeld and Seskin, 1982) is likewise frequently used to value mortality. A variety of methods such as discounting foregone income or using wage differentials between occupations with varying risks have been used to infer the value individuals place on mortality risk. Avoidance of death caused by foodborne illness does not appear in the literature (Antle, 1998). Willingness to pay for food safety has been evaluated using contingent valuation surveys or contingent valuation with experimental methods. Other studies use socioeconomic variables such as age, income, gender, and education to explain the variation in valuations but the results are inconsistent.

Assigning monetary values to certain types of adverse outcomes (or avoided outcomes) is sometimes difficult, morally objectionable, or both. For example, it can be both difficult and objectionable (to some or many stakeholders) to assign a monetary value to avoiding a premature death. Cost-effectiveness (C/E) analysis can be of assistance in *ranking* the wisdom of competing policy options to address a public health problem by leaving the adverse outcomes avoided in their natural units. C/E analysis cannot, however, tell you whether the option identified as “best” among several is actually the “best” or the “least worst.” That is, a particular policy approach to a problem might be better than the others considered, but it still might impose costs that exceed the benefits.

At least two other methods have been employed to improve the acceptability of outcome-cost comparisons. One is the use of outcome measures such as Quality Adjusted Life Years (QALYs) and Healthy Year Equivalents (HYEs), which essentially transform morbidity and mortality measures into quality- or health-adjusted life years. Many consider these measures to be more relevant and acceptable for decision making. Another approach is a class of techniques known as “risk-risk” or “health-health” analysis (Lutter and Morrall, 1994). In effect, these approaches attempt to give decision makers a method for weighing the costs of a policy with the expected benefits, not by monetizing the outcomes but by *demonetizing* the costs. Risk-risk and health-health analysis begin with the premise that policies designed to lower particular risks unintentionally raise other risks through one or several mechanisms. This way, the intended policy effects (benefits) and the unintended policy effects (costs) are both expressed in physical units (such as life years gained) in a way that allows decision makers to better see the tradeoffs of implementing the policy. Kuchler et al. (1999) present an illustration of health-health analysis applied to policies to reduce foodborne illness.

Economic analysis to inform decision making should do several things. It should identify the distributional consequences of proposed actions. Effects on both consumers and producers as well as deadweight losses should be evaluated. Likewise, the incremental benefits and costs associated with alternative policies should also be identified. The analyses should present best estimates along with a description of the underlying uncertainty whenever possible. As with other tools that inform risk management, the analysis must be transparent. Finally, the economic analysis does not make the decision but is one of several sources of valuable information for guiding decision making.

2.3 GOAL 3: RISK COMMUNICATION

2.3.1 Strategic Element 3.1—Communicating Risk

Research Review Question

What considerations need to be taken into account and what challenges need to be faced when communicating risk?

Summary of Findings

The literature consistently emphasizes that objective risk and perceived risk may be disparate and identifies several factors that affect public perception of risk. Challenges include how to incorporate and present information that describes the continuum of risk, increase the public's familiarity and comfort with risk measures and uncertainty, and counter or prevent panic or conversely fear-induced apathy. Special efforts need to target training of both technical and non-technical individuals in risk communication in general and crisis risk communication in particular.

Description of the Issue

The renewed interest in risk communication has brought with it a shift in our risk communication paradigm. The old model of risk communication involved a passive and unilateral flow of information stemming primarily from technical experts and with little dialogue occurring between the government and the public. However, in our current climate, the public has begun to question the information presented to them, expressed an interest in risk assessment and risk management, and taken the scientific information presented to them to arrive at their own evaluation of policy alternatives. In response to the need for information and debate, a new risk communication paradigm has emerged that consists of an interactive exchange of information and opinions, and multiple messages about the nature of risk as well as legal and institutional risk management issues.

Risk communication efforts are affected by many variables, and identifying and understanding these factors is an important component to ensuring the success of risk communication efforts. One variable of interest concerns what influences the public's perception of risk. Sandman (1987) has identified several factors that affect public perception (termed "outrage" to distinguish it from the scientifically-grounded terms "hazard" and "risk"), including the following:

- Process—The public is generally willing to accept higher risks when it is involved in the decision-making process but tend to be uncomfortable with decisions made on their behalf without their input.
- Control—Having personal control imparts a general feeling of safety since people trust their own instincts in this regard more than they would trust the instincts of others.
- Voluntariness—Risks that are chosen are generally perceived as safer than those that are imposed.
- Fairness—The perception of an unequal distribution of risk generally evokes outrage and ultimately a perception of greater risk.
- Familiarity—Exotic risks tend to be perceived as more dangerous than familiar risks.
- Community history—A history of risk-related problems and the satisfactory/unsatisfactory solution of those problems will influence the outrage factor.
- Social environment—The nature of the community will influence how residents respond to potential threats.

Unfortunately, the outrage factors identified by Sandman (1987) are often not represented to any extent in scientific and technical determinations. Technical risk experts are trained to characterize objective risk or "theoretical risk" but not necessarily subjective or perceived risk (Scherer, 1990). Given the disparity between objective and perceived risk, it is not surprising that risk communication often breaks down. Presentations of scientific and technical risk often fail to include information or discuss those risks in a way that the public considers relevant. Hence, the information presented is viewed as incomplete. Technical experts may likewise find public skepticism inexplicable. Under these conditions, both actors in the dialogue are likely to leave disappointed and suspicious of the other.

Challenges to risk communication can exist even when scientific information is abundant because it will be accompanied by some degree of uncertainty (otherwise there would be no risk). Ideally, information on risk should be presented as an expected outcome or range of expected outcomes with attendant uncertainties. However, the public is generally uncomfortable with probabilistic information. Although they may feel at ease with the notion of normal distributions with respect to height, for example, a normal distribution of risk will not generate the same level of comfort. However, if the public is to have an informed role in a risk communication dialogue, it is important that risk and uncertainty are introduced into the dialogue. The task for technical experts is to be able to present such information to the public in a way that can be understood.

There are other compelling reasons for overcoming the difficulties of explaining uncertainty to the public. We may have limited understanding of certain aspects of food safety, but we do know that risk is not binary (safe or not safe) and that risk exists as a continuum. Although we interact with “continua” all the time (for example, the spectrum of light), there is a strong tendency to divide it into a small number of manageable units (i.e., seven colors of the rainbow). The less comfortable we are with that “continua,” the more we simplify by decreasing the number of discrete intervals. With regard to the continuum of food safety, the tendency is to categorize food as safe and not safe. Risk communication efforts need to emphasize the continuum of risk.

Another challenge for risk communication is the unequal distribution of interest over time. During a food scare, an intense amount of interest and thus media coverage develops. However, once the food scare recedes from public memory, it is often difficult for risk communicators to get coverage. There are other challenges in addition to the inherent difficulties presented by uneven interest over time. Oftentimes when food scares occur, information needed to explain the situation might still be in the process of being generated. Unfortunately, this is precisely when the public is demanding answers. Crisis communication is further jeopardized if the initial response of risk communicators was intended to calm the public. When the crisis continues and worsens, the public can grow skeptical of risk communicators. Examples of such situations include alar in apples in the United States, *Salmonella* Enteritidis in eggs, and BSE in beef in the United Kingdom. Risk communication during food scares or crises are different enough that those situations require special consideration and preparation.

Yet another challenge to risk assessment is the increasingly overwhelmed feeling that the public is experiencing because of the frequent number of food scares in recent years ("hazard fatigue"). Conley (1998) suggests several methods to reinvigorate a public that is weary from numerous food safety scares. The first is the use of risk communication to provoke sufficient concern in the public without causing either panic or fear-induced apathy. Sandman (1987) has suggested that people view voluntary risks as less threatening than involuntary risks. Thus, providing consumers with specific actions that help them control the risk of foodborne illness (i.e., change involuntary risks into voluntary risks) may diminish the perceived risk. Information presented to consumers must be practical and consistent. Whenever possible, messages should be targeted with specific demographics in mind to be most effective.

Other methods for communicating risk have included the use of risk ladders where risk estimates are arrayed with low levels at the bottom and high levels at the top. Studies have shown that the use of a risk ladder can significantly influence risk perception; however, the literature surrounding the effect of risk ladders on mitigation intentions has produced ambiguous results (Sandman, Weinstein, and Miller, 1994).

2.3.2 Strategic Element 3.2—Consumer Attitudes, Knowledge, and Practices

Research Review Question

What demographic factors are associated with consumer attitudes, knowledge, and practices for purchasing, preparing, and consuming food safely?

Summary of Findings

The literature emphasizes that demography and lifestyles of U.S. consumers have changed dramatically over the past two decades in ways that significantly affect food safety. The continuing evolution of American lifestyles has definite implications for what consumers eat, where food is obtained, how food is prepared, and where food is prepared—all important dimensions for food safety. The literature reviewed to date does not consistently identify demographic groups appearing to exhibit strongly superior or inferior food safety knowledge or practice. Much of what is known about demographics and food safety is based on self-reported survey data. Only a handful of consensus conclusions about how demographic factors may be associated with consumer attitudes, knowledge, and practice concerning food safety have emerged in the literature over the past decade:

- Women are generally more likely to know and use good food safety practices than men.
- Men under age 30 are generally less likely to know and use good food safety practices than any other group.
- Based on self-reported behavior in surveys, up to one-third of consumers use unsafe food hygiene practices.
- The overall level of knowledge and experience with safe food practices has declined over the past two decades, regardless of demographic group.

Description of the Issue

The literature shows researchers agree that important societal changes over the past two decades have changed attitudes, knowledge, and practice concerning food purchase, preparation, and handling. The U.S. population has increased 10 percent since 1980 while family size decreased during the 1980s from 2.8 to 2.6 persons. The decline in family size, an increase in single heads-of-household, and more families with both parents working outside the home have all been cited as reasons leading to less time spent on food shopping and preparation. The proportion of children shopping for and preparing their own food has also been trending upward over time.

About 70 percent of women ages 25 to 44 are in the workforce and 75 percent work full time. Although 85 percent of employed women shop and cook, most spend less than 30 minutes preparing each meal and 20 percent spend less than 15 minutes (Collins, 1997). Overall, consumers spend less time on food preparation. The clear trend of consumer behavior is toward greater use of convenience foods, faster food preparation, and use of foods that may be partially cooked and may require special handling for safety. A final but highly significant societal change is the greater proportion of people at increased risk for foodborne illness (e.g., people with immunosuppression and the elderly) (Knabel, 1995). Yet there is little or no evidence that groups at higher risk of serious illness from foodborne pathogens have greater knowledge about food safety or routinely use safer food preparation and handling practices. For example, Heathcock et al. (1998), who surveyed 77 HIV-positive patients receiving treatment from a single hospital in the United Kingdom, report that only 36 percent had modified their diet for egg consumption and even less did so for soft cheese, pate, and cook-chill foods.

Preferences for quick methods of food preparation, convenience foods, fresh, “fresh-like,” and minimally processed foods have increased. Such preferences have led to proliferation of new processing, preservation and packaging techniques coupled with new channels of distribution for ready-to-eat or ready-to-heat foods—some of which have built-in food safety risks (USDA, 1996; Collins, 1997).

Changes in family structure and expansion in selection and availability of convenience foods have led to a reduction in widespread education and training of children and young adults about proper food handling and preparation practices, which may have encouraged growing complacency about food safety. People age 35 and younger have the lowest level of knowledge about food safety terms and concepts (Williamson, Gravani, and Lawless, 1992).

Because of changing American demographics and consumer behaviors, the traditional dichotomy of food-at-home vs. food-away-from-home is no longer an adequate taxonomy. A broader model that includes (1) where food is purchased, (2) where food is prepared, (3) who prepares food, and (4) where and how food is consumed may offer a more useful taxonomy for understanding associations among demographics, consumer behavior, and food safety risks. For example, about 50 percent of the food purchased from the food service sector (restaurants, pizzerias, fast food stores, and ready-to-eat/ready-to-heat counters in grocery stores) is “take-out,” and much take-out is eaten at home. On the other hand, about 10 percent of food purchased in retail stores is eaten somewhere other than home, and about 24 percent of fast food and pizza purchases are taken home to eat (Carlson, Kinsey, and Nadav, 1998).

The popular impression that a little more than half of America’s food is not purchased in retail food stores is misleading because it is based on expenditure data instead of quantity data. From 1960 to 1997, the percentage of the U.S. food dollar spent in the food service and restaurant sector grew from 26 percent to 46 percent, implying that food purchased at retail food stores fell from 74 percent to 54 percent. But measured by weight, 72 percent of the food Americans eat is still purchased in retail food stores (supermarkets, grocery stores, warehouse stores, convenience stores, drug stores, gas stations, bakeries, delicatessens, seafood stores, ethnic food stores, health food stores, commissaries, produce stands, and farmers’ markets); 14.5 percent is purchased at restaurants or fast food establishments; and nearly 13.5 percent is obtained from other sources such as vending machines, taverns, cafeterias, common office trays, gifts, and home gardens (Carlson, Kinsey, and Nadav, 1998).

Carlson, Kinsey, and Nadav (1998) report that age of the consumer is the primary demographic variable associated with food purchase behavior. Income and family composition also play a role but to a much lesser degree. Households with children tend to purchase more of their food in stores than the general population. Households with higher incomes tend to purchase more of their food in the food service and restaurant sector. Single persons of all ages tend to consume more food from restaurants, fast food, and pizza establishments than the general population. Young adults (ages 19 to 29) get less food from stores (59 percent) than any other age group. Persons over age 65 get most of their food (81 percent) from retail stores.

The literature offers a fairly small number of survey studies conducted over the last decade that seek to identify demographic factors that may be associated with food purchase, preparation, and handling. Several studies are based on data from self-reported surveys that ask respondents to recall food consumption and food hygiene practices over a 1-, 2-, or 3-day period. A few studies track food consumption behavior in panel diary studies over as many as 14 days. A few studies used national samples balanced to 1990 Census data, while others use smaller regional or state-based samples.

Researchers have included a variety of demographic variables in studies aimed at identifying associations with attitudes, knowledge, and practice concerning food purchase, handling, and consumption. Demographic variables studied include age, income, family composition, family size, gender, education, urbanity, employment, race, ethnicity, region, time-of-year, and day-of-week. But few studies are directly comparable because they use different data sources, different measures of variables, and different analytical methodologies, which may partly explain why so few consensus conclusions are available.

Ralston (1995) points out that consumption frequency of high-risk foods is an important variable for assessing food safety risk. An ideal database would include consumption frequency data on the following high-risk foods: raw or rare hamburger or ground beef; raw oysters, clams, and mussels; undercooked chicken or turkey; eggs with runny yellow or white parts; raw fish; foods made with uncooked eggs (Caesar salad, Hollandaise sauce, homemade ice cream, mayonnaise); and raw unpasteurized milk. Demographic variables that Ralston suggests would be useful to identify how and where individuals consuming high-risk foods can be reached include gender, income, education, marital status, geography, ethnicity, urban/rural orientation, employment, and frequency of away-from-home consumption.

Ralston (1995) assessed dietary intake survey data available with demographic information and large sample sizes that would be sufficient for risk assessment and identifying demographic associations. She concluded that the Continuing Survey of Food Intake by Individuals (CSFII) and the National Health and Nutrition Examination Survey have sufficient sample sizes. To estimate the smaller consumption frequencies of raw foods that are typical, the proprietary survey by the Market Research Corporation of America, which uses 14-day dietary intake data, would be useful.

Carlson, Kinsey, and Nadav (1998) conclude that CSFII is the only publicly available source of data that includes the full range of quantities of foods individuals eat, when and where they eat it, and where they got it. These data offer a richer base of information of overall food consumption behavior than market-level data based on sales, but CSFII does not include expenditure or price information, which limits its usefulness for economic analysis.

Several researchers identify predominant unsafe factors or practices that appear to be common among consumers. Table 2-2 lists the top 12 factors related to mishandling or mistreatment of food in the home. These factors contributed to 345 outbreaks of foodborne disease in the United States between 1973 through 1982 (Bryan, 1988).

Specific unsafe consumer practices frequently studied in the literature include (Albrecht, 1995; Collins, 1997)

- failure to wash hands before handling food,
- reusing cutting boards without washing after cutting meat,
- eating undercooked hamburger,
- eating raw molluscan shellfish,
- eating raw eggs, and
- holding food at room temperature too long before eating.

In one of the few studies of household behavior that collected observational audit data instead of self-reported survey data, Daniels (1998) made a distinction between “critical” and “major” violations of food safety practices. Critical violations, defined as those that by themselves can cause foodborne illness, include

- cross-contamination;

- inadequate hand washing;

Table 2-2. Top Twelve Factors Contributing to Outbreaks of Foodborne Disease in Homes[a]

Risk Contributing Factor	Percent[b]
Use of contaminated foods or raw ingredients	42.0
Cooking to inadequate temperatures	31.3
Obtaining food from unsafe sources	28.7
Improper cooling	22.3
Lapse of time between preparation and eating	12.8
Contamination by colonized food handlers	9.9
Non-food mistaken for food	7.0
Improper fermentation	4.6
Inadequate reheating	3.5
Toxic containers	3.5
Improper hot holding	3.2
Cross-contamination	3.2

[a]Table adapted from Knabel, 1995, p. 127.

[b]Percentage exceeds 100 because multiple factors contribute to single outbreaks

- refrigerator temperature above 45°F;
- eating food from damaged packages or cans;
- food preparation or handling by sick, symptomatic, or colonized persons;
- improper cooling of leftovers (where proper practice is defined as cooling to 70°F within 2 hours followed by cooling to 41°F or less within an additional 4 hours for a total of no more than 6 hours cooling time); and
- improper hot holding of cooked food at temperatures below 140°F.

Major violations, which Daniels defines as those that are very unlikely to cause foodborne illness, include

- refrigeration of leftovers in a large container,
- not regularly using a thermometer to measure food temperature,
- product past “use by” or “safe use” date,
- refrigerator temperature from 41°F to 45°F, and
- improper thawing (where proper procedures are defined as thawing in a refrigerator, under running drinkable water at

70°F or less within 2 hours, as part of cooking, or in a microwave with cooking following immediately).

Although the study did not look for attitude or behavioral differences by demographic characteristics, Daniels concludes that fewer than 1 percent of the 106 households observed met the minimum criteria for acceptable performance. He further concludes that improvements are needed in four main areas: avoiding cross-contamination, washing hands, cooking to appropriate temperature, and cooling leftovers properly.

In another observational study, Griffith, Worsfold, and Mitchell (1998) observed 108 meal preparations by a convenience sample of women recruited from churches and social organizations in the United Kingdom. For each meal preparation, Griffith, Worsfold, and Mitchell computed a "food safety risk" (FSR) score based on a defined demerit system for particular food safety violations. More egregious violations carried a greater number of demerits. Griffith, Worsfold, and Mitchell's study, which included only a small number of demographic categories (age and five socioeconomic categories), found no statistically significant correlations of FSR by demographic group and concluded that no distinct group has a potentially higher risk of foodborne illness.

Klontz et al. (1995) report that a few high-risk practices appear to be common in the general population, particularly among men and young adults. Specific practices cited were eating raw or undercooked eggs, undercooked hamburgers, and raw shellfish; and cross-contamination through inadequately cleaning cutting boards. In their study based on an FDA telephone survey, 53 percent of respondents consumed raw eggs, 23 percent consumed undercooked hamburger, 17 percent consumed raw clams or oysters, and 8 percent consumed raw fish. A quarter of respondents reported reusing cutting boards exposed to raw meat or poultry without washing the boards with soap or bleach. Respondents with education beyond high school were more likely to report high-risk food behaviors. Race was not related to most high-risk food behaviors, but white respondents were more likely to report eating raw eggs and undercooked hamburgers. Consumption of raw mollusks is more prevalent among persons residing in coastal regions.

Albrecht (1995) studied food safety knowledge and practice of U.S. consumers and found that *knowledge* of food safety tends to be higher among women, more educated persons, and those who live outside the city limits. Age, employment status, and number of meals prepared were not statistically significant in the study. Albrecht also found that *practice* of food safety tends to be lowest for males and people ages 19 to 30. More statistically significant associations with demographic factors were found for *practice* of food safety concepts than for *knowledge* of the same concepts. In particular, gender and age were the two most prominent variables showing association with food safety practice. Albrecht concludes that consumers tend to be confused about food quality versus food safety and further suggests that the distinction between food quality and food safety, and what constitutes each, should be clearly explained in food safety education programs.[1] Also, while consumers appear to be informed about food safety concerns with certain specific foods (e.g., potato salad and cream pies), they do not necessarily know or understand why these foods pose food safety issues.

Altekruse et al. (1995) found a definite gap between knowledge and practice of food safety concepts. In that survey, 80 percent of those who prepare food knew that hand washing reduces the risk of food poisoning, but only 66 percent washed their hands after handling raw meat or poultry. Eighty percent of those who prepare food knew that serving steak on a plate that has held raw steak increases the risk of food poisoning, but only 67 percent cleaned a cutting board after contact with raw meat or poultry. Males, people younger than 30, people with more than 12 years of education, and people who prepare food infrequently appear to have more conspicuous differences between knowledge and practice of safe food handling. Frequent food preparation, gender, and age—variables that may indicate food preparation experience—were not associated with adequate cooking of meat in the study.

[1]Food quality refers characteristics of food such as taste, appearance, freshness and nutritional characteristics (often readily discernible) on which consumers base their food purchase decisions. In contrast, safety characteristics of food, which relate to the presence of foodborne hazards and their associated public health risks, often cannot be discerned. A more detailed discussion of this distinction is presented in Section 2.2.2, Strategic Element 2.2—Market Failure and Regulatory Solutions.

In a second study, Altekruse et al. (1999) reported that risky food-handling and food consumption behaviors are common. This large, multistate survey of nearly 17,000 households using the Behavioral Risk Factor Surveillance System (BRFSS) data found that

- men and young adults are more likely to report risky behaviors;
- risky behavior tends to increase with socioeconomic status;
- young men are more likely not to wash hands and cutting boards;
- African-Americans are less likely to consume rare hamburger;
- about 50 percent eat undercooked eggs (no demographic associations);
- male, young, or middle-aged adults with higher socioeconomic status are more likely to eat raw oysters than are Asians and Hispanics; and
- drinking raw milk is more likely among young adults, Hispanics, and persons of lower socioeconomic status.

Bruhn and Schutz's (1999) mail survey of 605 households, which did not report results by demographic categories but for the whole sample, found that

- consumers consider themselves informed about food safety, but 20 percent do not know how to reduce risks from bacterial hazards;
- consumers are knowledgeable about selection and cooking specific foods, but safety mistakes are made;
- education should emphasize temperature control and sanitation; and
- consumers tend to be unaware that food that looks good and smells good can contain pathogens.

Maciorowski, Ricke, and Birkhold (1999a, b) surveyed 296 people in a convenience sample of people shopping for food in grocery stores in three Texas cities. In their study, they looked for differences in household poultry handling practices (e.g., days of storage before eating, thawing method) by gender, ethnicity, education, and language preference (Spanish or English). They found that from 33 percent to 58 percent of survey respondents thaw poultry unsafely, depending on demographic group. Hispanics, young people, and the less educated were more likely to thaw poultry inappropriately. More males and minorities store refrigerated poultry beyond the recommended time before eating.

Zhang, Penner, and Johnston (1999) surveyed 834 Kansas households by telephone to explore the prevalence of consumption of home-canned vegetables, raw or rare hamburger, eggs, or unpasteurized milk. The study looked for differences by the following demographic categories: age, gender, urbanity, marital status, income, education, body mass index, children at home, and age of child. Key findings were that eating home-canned vegetables is associated with rural residency, low income, and families with children ages 13 to 17; Kansas households are much less likely than other populations to eat undercooked hamburger; and eating undercooked eggs is very common among Kansas households but less so among the elderly Kansas population.

In May 1996, the Food Marketing Institute (FMI) conducted a series of consumer focus groups to explore the importance of food safety to consumers and identify barriers to safe food purchase, handling, and preparation (Collins, 1997). FMI found that the way in which consumers manage food safety reflects years of conditioning, observation, and reinforcement (or lack thereof) from mothers and grandmothers. Consumers tend to link safety to fresh food and tend to believe that cooked food is safer than raw food, regardless of handling.

Regardless of their demographic characteristics, consumers have demonstrated poor ability to associate unsafe food practices with specific episodes of foodborne illness, which may be an impediment to consumers learning and adopting safer food handling and preparation practices (Fein, Lin, and Levy, 1995). In a telephone survey of 630 households, Schafer et al. (1993) found no demographic relationships with food safety concerns. They also reported that respondents had much greater concern about contaminants than pathogens in food. The public generally believes that most foodborne illness originates somewhere other than home (particularly restaurants). Although 80 percent of *reported* foodborne illness outbreaks occur outside the home (CDC, 1996), most experts think that most cases of foodborne illness originate from foods prepared at home (Fein, Lin, and Levy, 1995; Knabel, 1995; Bean and Griffin, 1990).

Carlson, Kinsey, and Nadav (1998) used statistical cluster analysis on the 1990-1991 CSFII data to delineate several categories of consumers based on where they got their food. The study looked for differences in consumer food consumption behavior and consumer demographics delineated by food source categories. Demographic variables studied were age, race, sex, meal pattern, income, education, occupation, employment, region, urbanity, and household size.

The “home cookers” category comprised 49 percent of the adult population and purchased 93 percent of their food from retail stores. The “fast food” category comprised 15 percent of the adult population and purchased 22 percent of their food from fast food establishments but purchased 61 percent from retail stores. The third largest cluster, labeled “high service,” comprised 10 percent of the adult population and purchased 43 percent of their food from restaurants but also purchased 47 percent of their food from retail stores.

Demographic characteristics of the top three clusters identified in the study are summarized qualitatively as follows (Carlson, Kinsey, and Nadav, 1998). The “home cookers” tended to be older individuals with less education, lower income, and higher unemployment who were less concerned with ease of food preparation and inclined to eat more grains, fruits, and milk and less vegetables, eggs, meat, and fat. The “fast food” cluster tended to be younger individuals coming from the Northeastern United States who had more education and were inclined to eat more meat and less fruit. The “high service” cluster consisted of more Anglo men with higher income employed as professionals, technical specialists, or managers/proprietors; were less concerned about price; and ate more meat and less fruit. The “fast food” and “high service” clusters tended to be more employed and more educated than the “home cookers.”

Carlson, Kinsey, and Nadav (1998) reported that all three clusters tended to eat fewer than three meals per day. The researchers found that households headed by males were the least likely to eat three meals per day (38 percent) while two-parent households were the most likely to eat 3 meals per day (45 percent). They further note that "a significant part of the American diet is snacks. Over 78 percent of the respondents ate between one and three snacks per day."

In the literature reviewed to date, all demographically-identifiable groups include consumers who exhibit a full spectrum of attitudes, knowledge, and practices concerning food purchase, handling, and preparation. But through an informal synthesis of the literature, two polar demographic profiles emerge that may be associated with food safety.

People who know and practice superior food safety tend to be females older than 30 who regularly shop for food and prepare meals at home for themselves and children. They tend to have less than a college education and live in more rural areas. They learned safe food practices from their mothers and grandmothers through on-the-job training and may have taken home economics in school. Good hygiene is a long-practiced habit that they do not necessarily associate with safe food handling. They tend to be part of a two-parent household with moderate income and may be employed or unemployed.

People who know less about food safety and engage in "poorer" food safety practices tend to be single, young adult males with higher than average income and a college education or beyond. They live in a suburban area and eat a higher percentage of their food away from home than the general population. They seldom prepare full meals, but when they do eat meals at home, they tend to select ready-to-eat or ready-to-heat items purchased from a retail grocery or convenience store. This segment of the population admits to rinsing—not washing—hands and cutting boards.

Of course, most consumers fit neither profile particularly well and use a mix of safe and less safe food purchase, preparation, and consumption practices. A compelling message that emerges from the literature reviewed is that the general state of food safety knowledge and practice in America can be improved considerably across nearly all demographic categories. The literature on the public health impacts and costs of foodborne illness also indicate that consumer educational efforts to promote safe food handling and food consumption practices may be enhanced if targeted toward demographically-identifiable groups with the greatest need for change.

2.4 ORGANIZATIONAL MODELS

2.4.1 Background

In an April 1999 report, the GAO described the efforts of four countries in consolidating their food safety activities: Canada, Denmark, Ireland, and the United Kingdom. Since the release of the report in April 1999, several other countries have initiated efforts to consolidate their food safety activities, including Australia and New Zealand in a combined effort, France, and the European Union (EU). This review updates the 1999 GAO report on the four countries and incorporates available information on the efforts of Australia, New Zealand, France, and the EU.

Canada

The government of Canada has consolidated all federally mandated food inspection and quarantine services into a single food inspection agency, the Canadian Food Inspection Agency (CFIA). This consolidation was intended to unify and strengthen the national food regulatory system. The government estimated an annual fiscal savings of $44 million as a result of eliminating interdepartmental overlap in areas such as enforcement, risk management, laboratory services, and informatics and communications systems (CFIA, 1999).

Prior to the creation of the new CFIA, three agencies had food safety responsibilities: Agriculture and Agri-Food Canada, the Department of Oceans and Fisheries, and Health Canada. Agriculture and Agri-Food Canada set standards for meat and poultry, inspected food products, reviewed product labeling, and registered feed and fertilizer. The Department of Oceans and Fisheries registered seafood establishments and inspected exports, vessels, and all shellfish. According to the GAO report (1999), Health Canada was responsible for recall, crisis management, non-federally registered establishments, and compliance and enforcement. In addition, Health Canada typically evaluated and set standards for food safety, audited the other two departments, and conducted risk assessment and analytical testing research to support regulations.

The new system consolidates food inspection and enforcement activities into one agency. Specifically, the new system integrates the delivery of inspection and quarantine services provided by Agriculture and Agri-Food Canada, the Department of Oceans and Fisheries, and Health Canada. Health Canada retains substantial responsibility for evaluating and setting standards for food safety, research, risk assessment, and risk management and assessing the effectiveness of the new agency's food safety programs. The CFIA officially began operations in April 1997 (CFIA, 1999).

In addition to the restructuring and scientific advances, the Canadian government has also explored options for modernizing the food legislation. CFIA, in cooperation with Health Canada, published a summary report on legislative renewal in October 1998. The proposed review includes new legislation that covers commodities in the food chain including agricultural inputs and animal and plant health.

Denmark

The Danish government consolidated its food safety activities during a 4-year period beginning in 1995 (GAO, 1999). Before consolidation, food safety activities were divided among three subunits: the Ministry of Health, the Ministry of Agriculture, and the Ministry of Fisheries. The Ministry of Health set food safety standards for inspection of retail, processing, and distribution establishments. The Ministry of Agriculture, among other responsibilities, inspected meat and poultry processing plants. The Ministry of Fisheries had authority for seafood including fishing vessels and processing plants (GAO, 1999).

The new ministry—the Ministry for Fisheries, Agriculture, and Food (MFAF)— comprises three administrations or directorates: the Veterinary and Food Administration (VFA), Plant Directorate, and the Directorate for Fisheries. The VFA has responsibility for ensuring food safety, preventing misinformation, controlling zoonoses communicable to humans, inspecting meat at all processing plants, inspecting fish imports and exports, and coordinating activities with the other agencies. The Plant

Directorate has responsibility for plant foods, farm subsidies, fertilizers, farm practice, and animal feeds. The Directorate for Fisheries has responsibility for inspecting fishing grounds, including fish farms. In 1999, the entire budget for MFAF was only 13.5 billion kroner (US $2 billion).

Danish food safety officials expected to create a more efficient and effective food safety system but did not expect any cost or personnel savings (GAO, 1999). Danish officials anticipated that food safety inspections would be more consistent, resulting in a more efficient and effective food safety system, and would enhance overall food safety by applying food safety measures from its origins to the table. In addition, the GAO report states that a 1995 report released by the Danish Academy of Science indicated that an administrative reorganization would improve the efficiency of the food safety system. The Academy noted four other advantages of consolidation: implementing risk-based inspection schemes (such as HACCP), shifting resources to areas of greater risk, improving international and EU interactions, and improving consistency of inspections.

Ireland

The Food Safety Act of Ireland established the Food Safety Authority of Ireland (FSAI) in January 1999 and provided for it to take over all the food safety regulatory functions of existing agencies such as health departments and health boards. The principal function of the FSAI is to ensure that food produced, distributed, or marketed in Ireland meets the highest standards of food safety and complies with legal requirements. To achieve this, the Authority holds a wide range of powers that enable it to trace all food products from “farm to fork” (FSAI, 2000). The Authority is an independent public body that is funded by a yearly budget out of the Department of Health and Children. According to the April 1999 GAO report, the FSA operated on a budget of 6.5 million Irish pounds (US $9 million) in the first year plus start-up and coordination costs of another 6.5 million Irish pounds.

According to the 1999 GAO report, the Authority’s organizational structure includes the Board, a Scientific Committee, a Consultative Council, and a Chief Executive. The 10-member Board provides strategic direction for the Authority. To help ensure that the Authority maintains a consumer protection focus, industry representatives are precluded from serving on the Board. The Board receives advice from a Consultative Council that consists of industry and consumer representatives appointed by either the Minister for Health and Children or the Board. The Scientific Committee that provides technical advice to the Board consists of 15 experts appointed by the Minister for Health and Children. The Committee has assistance from 85 scientists who serve on 6 subcommittees and 10 working groups.

The FSAI also controls enforcement activities within Ireland. This includes all EU vertical and horizontal food law. To do this, the Authority has contracts with the 43 different agencies that enforced food law prior to the Authority. The Department of Agriculture, Food, and Rural Development (DAF) and local authorities (32 in all) control veterinary regulations through both permanent and temporary veterinary inspections/inspectors. Fisheries legislation is enforced by the Department of the Marine. Hygiene regulations are enforced by six regional health boards (now nine) using environmental health officers. There are also contracts with the Radiological Protection Institute and Department of Trade (for labeling regulations). Each contract outlines the work to be completed, specifying what an agency will do, what resources they will do it with, and how they will report to the FSAI. Contracts were established for a 3½-year period with yearly review. Government departments, not the FSAI, directly fund the work of the agencies. The FSAI budget is for operational requirements only (Anderson, 2000).

Before FSAI was created, food safety activities within Ireland were fragmented across more than 50 agencies. The Ministry of Agriculture inspected farms, abattoirs, and some other meat processing plants. The Ministries of Environment, Public Enterprise, Marine, Trade, Enterprise and Employment—in addition to eight local health boards—had various responsibilities related to food safety (GAO, 1999).

United Kingdom

The White Paper, “The Food Standards Agency: A Force for Change,” published in January 1998, sets out plans for a new public body that will transform the way that food safety and food standards are handled (UK MAFF–JFSSG, 1998). In 1999, the United Kingdom passed the Food Safety Standards Act, which authorizes a single agency with responsibilities for rule making, enforcement, surveillance, and research with regard to foods. The Food Safety Agency (FSA), the agency authorized by the Act, will be accountable for food safety from its origin through delivery (farm-to-table). The FSA will have authority to set and enforce standards, conduct research and surveillance, meet with international bodies, and coordinate with local authorities. The enforcement jurisdiction of the agency will include wide latitude to intervene in farm practice. However, the agency will not take over existing enforcement responsibilities of authorities of local outbreaks; these will continue to be managed by local authorities.

Before the FSA officially started on April 1, 2000, the U.K. government established the Joint Food Safety and Standards Group (JFSSG) in September 1997. The JFSSG comprises officials from MAFF and the Department of Health who report jointly to both ministers. The JFSSG formed the core of the FSA before it was established. Thus, the MAFF began transforming the food safety system before the FSA officially existed. Specifically, the JFSSG announced three new measures.

First, the MAFF plans to strengthen enforcement of meat controls (UK MAFF, 2000c). The new regulation adds several new provisions. In licensed facilities, it allows Meat Hygiene Service (MHS) staff to prohibit operation if meat has not been produced in accordance with the regulations (rather than just if the meat is unfit). In unlicensed facilities, it authorizes local enforcement officers to seize illegally produced meat (e.g., carcasses produced without inspection) in outside licensed facilities. The new regulation also allows the Minister to suspend licenses under serious circumstances, speeds up the appeal procedure, and lets the government recover charges for inspections at fresh meat repacking centers. The MHS, currently an agency of MAFF, will become an agency of FSA.

The MAFF also declared a move to reduce inspection burdens (UK MAFF, 2000a). In essence, the MAFF will coordinate inspection visits and checks with its agencies; the Intervention

Board; Agriculture Departments in Scotland, Wales, and Northern Ireland; and the local authorities.

In another press release, the MAFF revealed a plan to cut red tape (UK MAFF, 2000b) by reforming procedures, implementing a risk-based system in the meat industry, and streamlining the inspection system to improve efficiency and transparency with less forms and inspections. Other changes include electronic submission of subsidy claims, consultation on the accelerated herd coverage of the cattle tracing system, and consultation on an independent appeals mechanism.

Australia and New Zealand

Australia–New Zealand Relations. The Australian New Zealand Food Authority (ANZFA) is a statutory authority operating under the Australia New Zealand Food Authority Act of 1991. ANFZA coordinates surveillance of food available in Australia, coordinates recalls, develops risk assessment policies for foods imported into Australia, develops Codes of Practice, sponsors food safety education initiatives, and conducts research that supports standards development (ANZFA, 2000c). ANFZA also works with a Council of Health Ministers to develop and maintain joint standards that regulate food in Australia and New Zealand. Exceptions for standards include hygiene standards, residues of agricultural and veterinary chemicals, and dietary supplements (NZ MOH/MAF, 1998).

Both the Australian and New Zealand governments emphasized sound regulatory principles that would eliminate unnecessary impediments for industry and costs to the community and ensure that the regulation is simple and unambiguous. As a result, the Australian and New Zealand officials signed a Treaty on joint food standards that went into effect in July 1996. The treaty directed ANZFA to review current food codes and develop a joint Australia New Zealand Food Standards Code to replace the existing separate food standards of the two countries. This review, which involved more than 70 evaluation teams, began in the early 1990s.

On March 15, 2000, ANZFA released a draft food standard code for public comment (ANZFA, 2000b) with a timetable for replacing existing regulations in May 2002. The rule retains simplified compositional standards, provides better consumer information, and ensures consistency in labeling (ANZFA, 2000a). The code comprises three sections: general provisions, food product standards, and food safety standards. The food safety standards put forth by ANZFA will only apply to Australia, as New Zealand government has maintained authority of food safety for New Zealand products. Similarly, the New Zealand government is streamlining its food regulations.

Streamlining New Zealand's Food Activities. The New Zealand government has two ministries that regulate food production and safety: the Ministry of Agriculture and Forestry (MAF) and the Ministry of Health (MOH). The MAF handles international negotiation, trade treaties, and the interface of food policy with trade policy. The MOH sets New Zealand standards, joint Australia and New Zealand standards, nutrition policy, strategic policy, and legislation (NZ MOH/MAF, 1998).

The New Zealand MAF and MOH are making progress on streamlining the country's food safety regulations, making them less complex and yet more thorough (NZ MAF, 2000). The New Zealand government currently regulates food production by three different Acts. Under existing regulations, the MOH regulates the producers of food for domestic consumption through the Food Act and the Food Hygiene Regulations. Dairy producers have to comply with the Dairy Industry Act, and the processors of meat products must meet the requirements of the Animal Products Act. The latter two Acts are administered by the MAF. These complex regulations make it costly for producers and processors to meet the requirements. These costs are inevitably passed on to the end consumer. While consolidating the food safety regulations, the New Zealand government intends to implement a risk-management approach that shifts responsibility to industry. In fact, the New Zealand government called for voluntary support of HACCP principles for a risk-management approach to food safety in 1996 (NZ MAF, 1996). The New Zealand government proposes that the long-term goal of consolidating the regulations is to make New Zealand food products safer to eat and to make food regulations easier and cheaper for manufacturers and producers to meet.

In addition to streamlining the food regulations, the New Zealand government announced plans to set up a single, separate Ministry to handle all food regulation and administration (NZ MAF, 1999). For now, the structure of the two Ministries remains in place. However, the New Zealand government is harmonizing the MAH and MOH as an interim measure while final decisions are made on future structures.

France

Based of a review of the health safety regulatory framework, the French government created several new agencies including the Agence Francaise De Securite Sanitaire Des Produits De Sante (AFSSAPS), the Institut de Veille Sanitaire (InVS), and the Agence Francaise De Securite Sanitaire Des Aliments (AFSSA). Each agency has responsibility for certain food- and health-related activities.

A law of July 1, 1988 provides for an agency in charge of all health products—the AFSSAPS. AFSSAPS is in charge of medicine, health products, cosmetics, dietary supplements, and therapeutic products and techniques (such as gene therapy). The Institute for Monitoring Medical Development, known as InVS, monitors and studies epidemiological trends such as outbreaks of foodborne illness and health effects of pollution.

The French Agency for Food Safety, AFSSA, was created in April 1999. AFSSA is a public institution placed under the equal supervision of the three ministries involved with food safety: Health, Agriculture, and Consumer Affairs. The AFSSA has a general mission of risk assessment of all aspects of the food chain, from raw materials to human consumption. These responsibilities include a wide scope of activities and cover several sectors including meat and non-meat food products, potable water, and animal foods and drugs.

The AFSSA advises the ministries regarding regulatory policy decisions, and the ministries are responsible for risk management and risk communication. Prior to the development of any food safety regulatory action, the Ministries of Agriculture, Health, Finance and Industry, and Veterinary Food Hygiene must conduct a compulsory consultation with the Food Safety Agency which then performs an analysis (risk assessment) of the activity. The analysis is then made public and open for comment (Mennecier, 2000). The responsible ministry uses the information gathered during the analysis and comment process as a basis for policy decisions.

Several ministries share responsibilities concerning food: Ministry of Agriculture, Veterinary Food Hygiene Services, Ministry of Finance and Industry (Directorate General CCRS), and the Ministry of Health (Directorate General Sante). The Ministry of Finance and Industry is an inspection agency that oversees quality, weights, and standards for all foods and services. The Ministry of Health has primary responsibility for environmental health with food being one part of those responsibilities.

European Union

The EU, formerly known as the European Community (EC), is a union of 15 independent states. The EU was founded to enhance political, economic, and social cooperation. Member states of the EU that have food safety agencies coordinate with the EU Food Safety Agency. Proposals for legislation come from the European Commission, but all member states vote on proposed legislation. Therefore, general legislation is at the EU level, but enforcement of legislation is at the level of member states. Legislation is not imposed on member states and not enforced by the EU, only audited by the EU. The commission can sue a member state for noncompliance at the court of justice. One such incident involved BSE and U.K. beef bans (Mennecier, 2000).

Since this BSE incident in Europe, the EU has moved to increase the impact of its activities on food safety standards in member states. This included the separation of scientific advice from legislature power. The primary risk assessment committees under the guidance of a steering committee reported into the Directorate Generale XXIV of Consumer Policy and Consumer Health Protection (DG-24). The European inspection activities were also moved into DG-24. However, DG-24 had no power to write legislation; basically it influenced legislature activities in other Directorate Generals such as DG-93 (Industry) (Anderson, 2000).

In 1999, the commissioners of the EU resigned and were replaced. Romano Prodi, the EU president, emphasized the commitment to food safety. Commissioner David Byrne, the new head of SANCO, has drafted a White Paper for Food Safety in the Community (Anderson, 2000), which the EU published on January 12, 2000. The White Paper puts forth a plan that will enable the EU to coordinate food safety in a more integrated manner in order to achieve the best possible level of health protection. This plan outlines guiding principles for the basis of a comprehensive and integrated approach to food safety.

According to the plan presented in the White Paper, the EU intends to improve information gathering and analysis in order to support proactive policy decisions. The plan calls for increasing scientific cooperation, establishing effective management for method development laboratories, expanding systems for scientific advice and networking, implementing a system for risk assessment data, and improving coordination for data collection and analysis. With regard to coordinating data management and analysis from public health monitoring, the plan suggests coordinating data from residues and microbiology monitoring, rapid alert systems, and environmental monitoring (currently all are separate). The EU will expand the scope of data coordination to include the Rapid Alert Systems to encompass animal feed. The EU will also integrate different systems such as the systems for transmissible diseases and for animal products stopped at EU borders.

The White Paper proposes establishing a new Authority that would become the scientific point of reference for the entire EU. The Authority would provide scientific advice, develop and operate monitoring and surveillance programs, communicate directly with consumers, operate emergency response systems, network for science and regulatory purposes, and interface with the commission. The EU Food Safety Agency Authority has responsibility for risk assessment and risk communication, but the member states have responsibility for risk management (Mennecier, 2000). The EU has already put forth a timeline to develop a proposal by September 2000, enact enabling legislation by December 2001, and begin a new Authority in 2002.

The EU proposes to update the existing regulatory framework. First, the EU will establish rules for hygiene, irradiation, labeling genetically modified (GM) foods, animal feed, and novel foods. The EU will also amend rules for undesirable substances, prohibited ingredients, contaminants, food additives and flavorings, food irradiation, novel/GM foods, dietetic food/food supplements/ fortified foods, labeling, and pesticides and residue testing. To update the regulatory framework conceptually, the EU will incorporate principles of food safety. These concepts include farm-to-table, operator responsibility, traceability, transparency, risk analysis, risk assessment and management, the precautionary principle, and other factors. Finally, the EU plans to develop a community framework of national control systems that will include operational criteria at the community level and community control guidelines. By updating the regulatory framework, the EU will account for technological developments such as GM foods, risk assessment, real-time surveillance, and advances in monitoring and detection techniques.

In addition to these regulatory changes, the White Paper states that the EU will address consumer information, nutritional policy, and international policy. The EU will enhance consumer information by promoting risk communication, facilitating a global dialogue, providing public hearings, and increasing interactions with stakeholders. The EU will clarify consumer information; for instance, the EU will codify the labeling directive and consider or revise specific provisions for misleading messages and novel food. In addition, the EU will consider developing a comprehensive nutritional policy and directive regarding dietetic foods, food supplements, and fortified foods. Finally, the EU will promote an international framework for food safety.

2.4.2 Conclusions

The 1999 GAO report discusses lessons learned by the four countries that have consolidated. These include building a concensus, obtaining additional start-up funding, recruiting strong leadership early in the process, and building in a means of evaluation. The GAO report also states that none of the four countries has developed data for evaluating the effectiveness of consolidation. An evaluation of the new consolidated system might include measures of effectiveness and a cost-benefit analysis. Criteria for measuring effectiveness might include trends in incidence of foodborne illnesses, consumer and industry perception, and bacterial levels and other hazards found in food products. A cost-benefit analysis would evaluate costs and identify potential benefits and value benefits if data are available.

3 Observed Research Needs

In this final section of the report, we present our observations on future research needs relative to the eight strategic elements studied in this evaluation synthesis. The observations presented in this section were made on the basis of the systematic review of available scientific literature on the eight strategic elements; an assessment of the methodologies used in those studies and the limitations of the research; an evaluation of the efficacy and effectiveness of each element and its potential contribution to the overall strategic plan based on the review findings; and an identification of gaps in our current knowledge base for food safety.

In Section 3.1, we describe an overall assessment of research needs relative to the eight strategic elements based on the findings from a critical literature review. The needs assessments are presented in sequential order corresponding to the strategic elements reviewed in Sections 2.1 to 2.3.

In Section 3.2, we detail our observations regarding future research directions and needs. The evaluation synthesis highlighted numerous areas of focus for future evaluation studies and research directions relative to the eight strategic elements under consideration. Hence, while the research needs outlined in Section 3.2 are numerous, they are not a comprehensive list of research needs. These observations represent only a subset of food safety research needs specific to the eight key food safety elements reviewed in this evaluation synthesis.

We feel that the observed research needs outlined in this section constitute the starting point of a two-fold process. The first step is the idea-generating and feedback phase (of which this list is a component) that addresses the research needs in specific areas related to microbiological food safety hazards. The second step, which is not addressed in this report, is to develop a procedure for prioritizing the generated list of research needs in line with the Food Safety Strategic Plan.

It is also important to note that there are already some ongoing efforts to address many of the research needs identified below. The efforts of numerous federal, university, and private-sector researchers could benefit from overall coordination within the context of the goals and objectives of a Food Safety Strategic Plan.

3.1 NEEDS ASSESSMENT OF FUTURE RESEARCH DIRECTIONS

3.1.1 Strategic Element 1.1—Emerging Foodborne Diseases

Existing gaps in our knowledge primarily surround our lack of understanding of the underlying mechanisms leading to the emergence of a foodborne pathogen. While research has helped to identify a number of risk factors that have been associated with emerging pathogens, retrospective studies on prototypical emerging foodborne diseases have provided little insight into the mechanisms of emergence. The use of observational epidemiological studies may help to focus research efforts on these underlying mechanisms. A consensus action plan outlining general research methodologies for emerging foodborne pathogens would enable the rapid implementation of specific prospective studies and other information-gathering activities that may shed light on the mechanisms of emergence in the face of the identification of a new foodborne pathogen.

The role of animal and human movement in emerging diseases is widely hypothesized, but research is needed to characterize the relationship in specific situations. Descriptive epidemiologic studies should identify specific movements of animals and/or people that were most likely to have promoted the emergence of a new foodborne pathogen. Case studies analogous to outbreak investigation methodologies would be most helpful in this regard. These case studies should also consider why the movement pattern changed and what other factors were altered to provide a favorable microecological environment for the emergence of a new foodborne disease.

Food safety professionals could benefit from training in the recognition of abnormal patterns of pathogen or disease occurrence throughout the farm-to-table continuum. Research into methods for describing real-time patterns of normal versus unusual pathogen occurrence, which lend themselves to field application, is necessary.

3.1.2 Strategic Element 1.2—Integrated Surveillance and Early Warning Systems

Our ability to establish disease trends, understand foodborne disease etiology, and use data to allocate public health resources is hampered by limitations in our current surveillance systems. Several evident surveillance gaps in our current system (e.g., linking on-farm and slaughter information) make it difficult or impossible to track hazards from the farm through consumption or to adequately link those hazards to public health outcomes. The absence of a cohesive surveillance system highlights the need for integrated information systems that link surveillance in animal and human populations, as well as cohesive national, state, and local foodborne monitoring systems. A review of the literature on early warning systems reveals that currently existing early warning systems are not oriented toward food safety, highlighting a need for research to develop such systems for food safety. A robust early warning system for food safety could signal the existence of untoward conditions in foods, their sources, and the processes that produce them before they become evident in the human population.

The lack of cohesive information systems across animal pathogens and human disease may point to the need for cross-disciplinary training in animal and human surveillance, with epidemiologists proficient in not only the principles of disease monitoring and surveillance but also the associated operational issues for setting up such systems in animals and humans. Electronic data systems that support cohesive surveillance programs are also lacking. Research needs include the development of integrated sampling designs (for on-farm, slaughterhouse, distribution, and retail) for adequately monitoring pathogens of public health concern.

3.1.3 Strategic Element 1.3—New Detection Methods for Microbial Hazards

The lack of rapid, inexpensive clinical diagnostic kits that remain relatively unaffected by the matrix, normal bacterial flora, and interference by food ingredients continues to pose an impediment to providing real-time assessments for managing foodborne hazards. Recent developments in immunologic- and molecular-based techniques and automated technologies may provide more timely and accurate characterization and identification of foodborne hazards. Genotyping methods may also herald the increasingly important role of molecular epidemiology in food safety.

A continuing need for research into methods for real-time detection of foodborne hazards exists, but researchers must also be encouraged to emphasize utility of the testing method, sampling design, and issues related to real versus apparent prevalence. Appropriate field applications for various detection technologies, such as the value and cost-effectiveness of inclusion of detection methods into a HACCP plan, also require further evaluation.

3.1.4 Strategic Element 2.1—Patterns of Foodborne Outbreaks

Changes in our production, processing, and distribution systems and consumption patterns have resulted in corresponding changes in patterns of foodborne outbreaks. Research efforts to characterize and quantify the shift from traditional “church-supper” outbreaks to widely diffuse outbreaks are needed. It is also necessary to elucidate under what circumstances a group of “sporadic” cases are truly sporadic in nature as opposed to an undetected outbreak.

Efforts to develop integrated information systems and incentive structures for data sharing among federal agencies, food producers, processors, distributors, and retailers are needed. These integrated systems would help in the identification of outbreaks and their sources, vehicles, and agents.

Outbreaks of unusual presentation need to be characterized more fully in order to enhance their rapid identification. Simulation models may be helpful in this regard.

3.1.5 Strategic Element 2.2—Market Failure and Regulatory Solutions

Numerous gaps exist in our current knowledge of the efficacy of various types of market interventions for improving food safety. These interventions include command-and-control (such as process standards, product or outcome standards, and mandatory disclosure) and incentive-based interventions (such as public provision of information, private bargaining, and product liability). Research is needed to evaluate the welfare gains and losses associated with various regulatory approaches to achieve food safety improvements. Such research should identify who bears the costs and the benefits of various intervention programs including an assessment of program administration costs. Because testing programs are playing an increasingly large role in food safety programs, an economic model of the benefits and costs of increased testing on risk reduction should also be developed to assess the impact of industry and government testing on costs of production and food safety standards.

3.1.6 Strategic Element 2.3—Comparative Risk Analysis and Benefit-Cost Analysis

There is consensus in the literature regarding the value of comparative risk analysis (CRA) and benefit-cost analysis in prioritizing efforts. Hence, a direct application of CRA to foodborne pathogens would point to the development of a risk ranking of various foodborne hazards and food processes to generate information about the relative risk to human health. A review of various government programs that were preceded by a CRA and/or benefit-cost analysis will assist in assessing the value of the information from these methods in decision making, program development, and resource allocation. These follow-up assessments should describe whether the information was used in decision making, how it was used, whether the information was appropriately applied, if the information helped to form a decision, and how it influenced the decision.

3.1.7 Strategic Element 3.1—Communicating Risk

The importance of risk communication, and particularly crisis risk communication, points to a need to train both technical and non-technical individuals involved in food safety in these areas. Risk communication challenges include incorporating and presenting information that describes the continuum of risk, increasing the public's familiarity and comfort with risk measures and uncertainty, countering or preventing panic or conversely fear-induced apathy, and continuing risk communication efforts once a food scare recedes from public memory.

Additional research should be targeted toward understanding the effect of various communication strategies on perceived risk and behavioral responses/changes. Communication strategies for consideration and evaluation in future research efforts should include both short-term (when a risk requires immediate communication or a crisis is present) and long-term (continual provision of information after a food scare is resolved) messages.

3.1.8 Strategic Element 3.2—Consumer Attitudes, Knowledge, and Practices

The importance of consumer behavior as it influences foodborne illness, and the wealth of research studies on consumer demographics and their interaction with consumer attitudes, knowledge, and practices make this area potentially ripe for metanalysis. However, much of what is known about demographics and food safety is based on self-reported historical-recall survey data, the most apparent methodological limitation of consumer research. Furthermore, public health data on morbidity/mortality with the underlying demographic information have not been adequately linked to, or used to validate, consumer studies to any extent.

Information obtained from demographic studies should be linked to population-attributable risk in order to estimate the magnitude of foodborne illnesses within identified high-risk groups or individuals with high-risk food preferences. Research questions that need to be addressed include who is taking high-risk behaviors with respect to specific foods with known risks; what is the underlying construct in high-risk behaviors; whether targeted risk reduction can be based on this information; and what proportion of foodborne illness could be prevented by targeting populations based on high-risk behaviors.

Follow-up studies should address the effectiveness of strategies on targeted populations. Future research should also address how to use the information from consumer studies to develop risk communication messages and targeted strategies for effective risk reduction.

3.2 RESEARCH NEEDS AND OPPORTUNITIES

This section details our observations regarding specific research needs and opportunities for enhancing our food safety knowledge base. These observed research needs are based on the findings from a critical review of the publicly available scientific literature and the needs assessment detailed in Section 3.1. Because this evaluation synthesis was primarily limited to microbiological hazards, the list presented below does not cover food safety in a comprehensive manner.[2] Neither do we consider it to be an all-inclusive list of food safety research needs relative to microbiological hazards. To the contrary, the observed research needs outlined below are provided with the intent of initiating a two-step process: (1) an idea-generating phase and (2) a prioritization procedure, with both phases ideally involving stakeholder input. We view this list of observed research needs as a first step toward the idea-generating phase. The second phase, the development of a procedure for prioritizing these research needs, is not addressed in this report but is conceived as a process consistent with the Food Safety Strategic Plan.

The observed research needs discussed below are categorized according to the following criteria:

- **Primary Research Needs**—areas where information gaps identify a potential role for additional research,
- **MetaAnalyses**—areas where research provides a sufficient base for conducting metanalysis, and

[2] For other perspectives on food safety research needs, see articles such as Cliver (1993) and Doores (2000). A more comprehensive view of food safety research needs could be established by incorporating information from such reports, guidance from the agencies involved in managing food safety risks, and input from stakeholders. However, such efforts are beyond the scope of this report.

Z **Further Evaluation Syntheses**—areas where evaluation syntheses may help to identify information gaps and research needs.

Some activities related to the research needs highlighted in the following section may already be ongoing.

3.2.1 Primary Research Needs

Develop an outline of the general research methodologies for emerging foodborne diseases that would enable the rapid implementation of specific prospective studies and other information-gathering activities that may shed light on the mechanisms of emergence. The objective of this initiative is to develop some specificity about how new pathogens enter the food chain.

Conduct descriptive epidemiologic studies to identify specific movements of animals and/or people or changes in animal or human demographic patterns, environments, or food product technologies that were most likely to have promoted the emergence of a new foodborne pathogen.

Identify methods for describing real-time patterns of normal versus unusual pathogen occurrence that would be easily adaptable to field applications.

Initiate a nationwide prospective cohort study to determine what proportion of all acute gastroenteritis cases are due to foodborne pathogens of major concern. This study could be conducted in collaboration with FoodNet active surveillance sites through routine collection of fecal samples from a random sample of all presenting cases of acute gastroenteritis. Each fecal sample should be examined for the presence of all major pathogens to the extent practicable within present technological and cost constraints.

Z Define the elements of and identify approaches for establishing a more robust early warning system for food safety that uses non-human indicators to signal a potential problem.

Z Develop electronic data systems, both hardware and software elements, that support cohesive surveillance programs at the federal, state, and local levels to enhance safety and shorten emergency response time.

Z Continue research in the development of rapid methods for real-time detection of foodborne hazards, expanding research needs to include consideration of the utility of the testing method, sampling design, and issues related to real versus apparent prevalence.

Z Identify appropriate field applications for various foodborne pathogen detection technologies. For example, would new testing technologies be a cost-effective component of a HACCP plan or a Quality Assurance Program?

- Conduct risk rankings for various pathogen–food product combinations to determine the subset with high-risk *or* high-consequence potential for foodborne illness. Considerations should include risk factors related to food sourcing, processing, and distribution; the consuming population; and potential public health outcomes.

Initiate research into the benefits and costs of increased testing on risk reduction and the impact of industry and government testing on the costs of production and on food safety standards.

Conduct a CRA to elaborate a risk ranking of various foodborne hazards and food processes. The risk ranking may also provide a basis for focusing further research efforts by targeting efforts toward high-consequence hazards and high-risk foods, processes, and populations.

Support research efforts that address effective strategies for risk communication in the short-term (when a risk requires immediate communication or a crisis is present) and long-term (continual provision of information after a food scare is resolved).

- Initiate a longitudinal study to generate data on the determinants of consumer behavior relevant to food safety.
- Conduct a prospective assessment of food intake that establishes an at-risk population to better define food-specific attributable risk. Ideally, such a study would be accompanied by actual food sampling to determine pathogen load. Enumeration of positive samples would also provide much-needed data for the development of dose-response relationships for use in risk assessment models.
- Develop and standardize methods for detection of viruses in food samples so that the extent of foodborne illnesses of viral etiology can be adequately assessed.
- Develop consistent, standardized demographic categories for use in research studies on food safety practices and knowledge to allow findings from multiple studies to be integrated into a comprehensive characterization of the consumer demographics of food safety.
- Initiate field and experimental studies to identify “critical violations” of source, handling, preparation, storage, or consumption of food—violations that *by themselves* can lead to foodborne illness or injury.
- Initiate research to establish the reasons why a gap between food safety knowledge and food safety practices exists in order to understand how the gap can be narrowed through educational or other initiatives.

3.2.2 MetaAnalysis

Initiate research programs that integrate the information from consumer studies into the development of risk communication messages and targeted strategies for effective risk reduction. Companion follow-up studies should address the effectiveness of specific messages and strategies on targeted populations.

- Develop a metanalysis of high-risk consumer behaviors so that risk management strategies can be targeted toward those high-risk subpopulations. Specific outcomes of interest for metanalysis include what are the significant high-risk behaviors, who is taking high-risk behaviors with respect to specific foods with known risks, and what is the underlying construct in high-risk behaviors.
- Develop a new taxonomy to replace the traditional "away-from-home"/"at-home" food consumption risk delineation. The new risk taxonomy, categorized by food product type and place of consumption, should be based on a metanalysis of consumer studies using demographic information such as age, gender, and education as well as consumer knowledge and practices such as hand washing, and cooking and storage temperatures.

3.2.3 Further Evaluation Syntheses

- Conduct evaluation syntheses of strategic food safety elements related to chemical and physical hazards in foods consistent with the goals and objectives of the Food Safety Strategic Plan.
- Develop strategies for a cohesive surveillance system that addresses existing gaps in surveillance for foodborne hazards and diseases. The objective is to link surveillance in animal and human populations by monitoring disease and/or hazard levels from the farm, slaughterhouse, processing, distribution, and retail through consumption. Strategies for building a cohesive surveillance system must consider linking existing national, state, and local foodborne monitoring systems.
- Identify alternative means by which multiple cases or multiple outbreaks can be rapidly linked epidemiologically. Further evaluation should include development of a ranking according to the alternatives' effectiveness across different hazards, an assessment of resources necessary for implementation, and a delineation of follow-up studies necessary for program evaluation.
- Perform a comparative evaluation of food safety programs to ascertain the efficacy of voluntary incentive-based approaches and mandatory requirements (using *Salmonella* Enteritidis or another hazard with a long-term, varied control program history) as the basis for retrospective and prospective analysis.

- Carry out a program evaluation using case study approaches examining the burden of costs as well as efficiency of incentive-based versus command-and-control programs.
- Incorporate into regulatory impact assessments an analysis of the distributional impacts (who bears the costs of and benefits from) of interventions and regulatory options, particularly those associated with command-and-control food safety regulation versus incentive-based interventions.
- Conduct follow-up evaluations of completed CRAs or benefit-cost analyses that preceded policy development. The follow-up studies should describe whether the information was used in decision making, how it was used, whether the information was appropriately applied, if the information helped to form a decision, and how it influenced the decision.
- Outline methodologies and conduct prospective studies to address the effectiveness of risk management strategies/programs developed for targeted populations/behaviors.
- Link consumer studies to population-attributable risk in order to estimate the magnitude of foodborne illnesses within high-risk groups or individuals with high-risk food preferences based on a metanalysis of consumer behavior, practices, and knowledge. Policy-relevant questions for evaluation synthesis could address how to focus risk reduction or intervention strategies based on this information.
- Conduct a critical review of the literature using biotechnology as the case study for evaluating the risk communication process. Successes and failures should be highlighted, and factors influencing risk perceptions should be identified.
- Conduct a critical review of the literature measuring the effect of various communication strategies on perceived risk and behavioral responses/changes. The review should focus on the determination of the effectiveness of particular strategies in producing a desired behavioral response in an identifiable population (i.e., what message affects what behavior in what subpopulation).
- Evaluate dietary information and consumption data from large population-based studies such as heart disease or diabetes nationwide research projects, or from large data collection efforts such as CSFII for utility in food safety studies related to identifying high-risk populations and behaviors.

3.3 NEXT STEPS

The list of observed research needs outlined in the preceding section is extensive but by no means comprehensive. We feel that our observations of the research needs relative to the eight strategic elements studied in this evaluation synthesis constitute the starting point of a two-fold process in developing a food safety research agenda, which would ideally involve stakeholder input. The first step is the idea-generating and feedback phase, of which this list is a component, addressing needed research in microbiological food safety hazards.

Because evaluation synthesis is a systematic method for summarizing, coalescing, and interpreting evidence of the efficacy and effectiveness of the strategic elements under review, it provides a solid foundation for identifying information gaps and directing future research efforts, all of which are critical to developing a research agenda. Hence, it becomes a useful mechanism in the first step of the process of generating a research agenda or focus.

The second step is the development of a process for and the prioritization of the generated list of research needs in line with a strategic plan for food safety. Although we do not address this second step in the evaluation synthesis, one of our project objectives was to develop a mechanism by which input and feedback could be obtained that would assist efforts to establish research needs and priorities. In this regard, RTI has developed an interactive web-based data collection mechanism that has potential applications in developing a food safety research agenda. The prototype was conceived as a potential research planning tool for inviting input, obtaining feedback, and ranking or prioritizing research needs and future research directions.

The interactive web-based application was developed with a focus on online strategies and web-based capabilities for the purpose of collecting and tracking rankings made by a selected group of participants. Respondents are given access to the “Food Safety Research Planning Web Site” through pre-assigned passwords. In the prototype system, users are requested to log in and rank the series of observed research needs under the three categories detailed in this report. For each category, respondents are presented with a simple interface that lists the identified research needs, accompanied by drop-down boxes from which they can select the number that they believe corresponds to the importance of each research need.

Users' responses are recorded and kept in a database. Users may re-enter the web application multiple times and revise their rankings as necessary. Upon re-entry, the application pre-fills the numeric drop-down lists with the user's previously ranked preferences. Users may then revise their rankings or leave them as they are. Input boxes are supplied for each category allowing users to input research needs that do not appear in the list to be ranked or to provide other relevant feedback. The application is built to handle an infinite number of respondents.

Storing respondent data in the database allows the administrators of the research project to generate reports and track progress. Administrators log in using a pre-assigned username and password, which allows them to access the application to produce reports of users' rankings. Summaries of user rankings can be obtained and present the most current information in the database such as the highest/lowest ranking received by a specific research need or the number of respondents who have ranked a specific research need as highest/lowest. Project administrators can also view summaries of other input and feedback from respondents and review them for relevance. Generated reports are tailored specifically to the requirements of the project's administrators. Additional reports can be implemented as needed at any time. All administrative reports are generated *dynamically* by pulling real-time data from the database and reflect the most up-to-date state of information contained in the database.

With the development of this prototype, we feel that an effective and timely mechanism for obtaining input toward establishing a food safety research agenda is in place. With minor modifications, the system could be ready for immediate use.

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Appendix A: President's Council on Food Safety's Draft Preliminary Food Safety Strategic Plan

The President's Council on Food Safety was established in August 1998 under Executive Order 13100 to strengthen and focus the nation's efforts to coordinate food safety policy and resources. On January 7, 2000, the Council released the *Draft Preliminary Food Safety Strategic Plan for Public Review*. The Draft Food Safety Strategic Plan includes the following three food safety goals and corresponding objectives:

- ***Goal 1: Science and Risk Assessment***
  - **Objective 1:** Strengthen the scientific basis for food safety policies and regulatory decisions through expanded surveillance and rigorous assessments of risk.
  - **Objective 2:** Expand surveillance and data collection capabilities for adverse human health outcomes related to the food supply.
  - **Objective 3:** Develop and implement a unified, risk-based problem-solving research agenda particularly aimed at bridging identified gaps.
  - **Objective 4:** Identify emerging and potential high-risk food safety threats.
  - **Objective 5:** Enhance scientific infrastructure and skills at federal, state, and local levels.
  - **Objective 6:** Evaluate research, risk assessment, and surveillance programs for their effectiveness in providing the scientific knowledge needed to develop and implement programs that assure maximum public health.
- ***Goal 2: Risk Management***
  - **Objective 1:** Identify areas where risk management gaps exist in the current food safety system.
  - **Objective 2:** Promote development and implementation of preventive techniques and controls using risk-based approaches and establishment of national standards, including performance standards, where appropriate.
  - **Objective 3:** Expand and enhance effective monitoring, surveys, inspections, and surveillance of foodborne illness and other health effects resulting from food safety hazards.
  - **Objective 4:** Identify food safety risks and violations of food safety standards through inspections.
  - **Objective 5:** Protect the food supply through consistent training and consistent enforcement of food safety laws and established regulatory requirements.

- **Objective 6:** Encourage the implementation of risk-based, voluntary approaches for improving food safety, where appropriate.
- **Objective 7:** Promote the development and transfer of new technologies and approaches to risk management directed at improving food safety.
- **Objective 8:** Identify and respond to food safety emergencies rapidly and effectively.
- **Objective 9:** Develop an improved system of assuring that foods being exported to the United States from other countries are produced under food safety measures that the United States concludes meet or otherwise achieve the appropriate level of public protection specified by the United States.
- **Objective 10:** Evaluate management of food safety risks.

- ***Goal 3: Risk Communication***
  - **Objective 1:** Sustain public confidence through effective, open, transparent, and timely information exchange regarding food safety risks, prevention strategies, and decision making.
  - **Objective 2:** Develop state-of-the-art science-based education and training programs for growers, producers, transporters, retailers, consumers, regulators, public health workers, and medical care providers—all persons along the farm-to-table chain—focused on prevention of foodborne illness and hazards.
  - **Objective 3:** Provide rapid access to information about food safety surveillance, hazards, outbreak actions, enforcement, and other food safety emergency activities through active outreach efforts.
  - **Objective 4:** Monitor and evaluate information and education programs to maximize public health.

The complete document, which details the action steps corresponding to each objective, can be viewed at www.foodsafety.gov/~fsg/cstrpl-3.html on the President's Council for Food Safety web site (www.foodsafety.gov/~fsg/presidentscouncil.html).